

Anna Sigríður Vernharðsdóttir

The efficiency of acupuncture for nulliparas in actuating cervical ripening and spontaneous labour after 41 weeks (\pm 2 days) of normal pregnancy: Pilot study

Dissertation submitted in part requirement for the Master in Midwifery of The University of Sheffield.

June 2008

Acknowledgements

I would like to thank the directors of Landspítali University Hospital in Reykjavík and the directors of the Primary Health Care of the Capital Area for the goodwill towards this study and giving me the opportunity to conduct the study within their organizations. My special thanks go to my supervisors, Roger Watson and Christine Ingleton. Their support and knowledge is precious. My special thanks also go to Helga Gottfreðsdóttir, midwife who took on the local responsibility for the study. Her inspiration and encouragement was important as well as her assistance regarding local practical things. My thanks go to Valgerður Sigurðardóttir, midwife for valuable assistance during the data collection. Finally, I wish to express my appreciation to all the women who participated in this study and to the midwives and the physicians at Landspítali University Hospital in Reykjavík who were so helpful during the data collection.

Contents

Abstract	9
<i>Background</i>	9
<i>Objective</i>	9
<i>Methods</i>	9
<i>Results</i>	10
<i>Conclusion</i>	10
1. Aims and purposes of the study	11
1.1 <i>Introduction</i>	11
1.2 <i>Background</i>	13
1.2.1 <i>Acupuncture</i>	13
1.2.2 <i>The researcher’s experience in the use of acupuncture and the use of acupuncture at Landspítali University Hospital</i>	15
1.2.3 <i>Beginning of labour and the mechanism of action of acupuncture on labour</i>	16
1.2.4 <i>Post-term pregnancy</i>	20
1.2.5 <i>Natural methods to induce or accelerate labour</i>	21
1.3 <i>Research objectives and hypotheses</i>	24
2 Literature Review	25
2.1 <i>Search strategy</i>	25
2.2 <i>Acupuncture and induction of labour</i>	26
2.3 <i>Influence of pre-labour acupuncture on duration of labour</i>	35
2.4 <i>Acupuncture to accelerate labour</i>	39

2.5	<i>Acupuncture points</i>	41
2.6	<i>Gaps in the knowledge</i>	41
3	Methodology	43
3.1	<i>Research approach</i>	43
3.2	<i>Inclusion and exclusion criteria</i>	43
3.3	<i>Sample</i>	44
3.4	<i>Gaining ethical approval</i>	45
3.5	<i>Research process</i>	47
3.6	<i>Concept definitions</i>	50
3.6.1	<i>Meridians</i>	50
3.6.2	<i>Acupuncture points</i>	51
3.6.3	<i>Cun</i>	52
3.6.4	<i>Active phase of labour</i>	52
3.6.5	<i>Cervical ripening</i>	53
3.6.6	<i>The Bishop score and the modified Bishop score</i>	54
3.6.7	<i>Estimated date of delivery (EDD)</i>	55
3.6.8	<i>Induction of labour</i>	55
3.6.9	<i>Spontaneous labour</i>	56
3.7	<i>Data collection and analysis</i>	56
4	Results	58
4.1	<i>Demographic information</i>	58
4.2	<i>Flow of participants</i>	58
4.3	<i>Time from randomization to the active phase of labour</i>	59

4.4	<i>Cervical ripening</i>	60
4.5	<i>Incidences of medical inductions and spontaneous labour</i>	62
4.6	<i>Duration of labour</i>	63
4.7	<i>Mode of birth</i>	64
4.8	<i>Use of pain relieving agents</i>	65
4.9	<i>Need for pharmacological agents and amniotomies for augmentation and induction of labour</i>	67
4.10	<i>Post-partum blood loss</i>	68
4.11	<i>Apgar score</i>	68
5	Analysis and Discussion	70
5.1	<i>Primary outcomes</i>	70
5.1.1	Hypotheses.....	70
5.1.2	Cervical ripening.....	71
5.2	<i>Secondary outcomes</i>	73
5.2.1	Mode of birth.....	73
5.2.2	Use of pain relieving agents.....	73
5.2.3	Need for pharmacological agents and amniotomies for augmentation and induction of labour	75
5.2.4	Post-partum blood loss.....	76
5.3	<i>Methodology</i>	76
5.3.1	Tools of data collection and data collection.....	76
5.3.2	The interventions.....	78
5.3.3	Control of other possible effects on the beginning of labour.....	80
5.3.4	Practical issues.....	81
5.4	<i>Implications for practice</i>	81

6	Conclusion and Recommendations	83
6.1	<i>Conclusion</i>	83
6.2	<i>Suggestion of further avenues for future research.....</i>	83
	References	85
	Appendix 1: Forms for data collection	95
	Appendix 2: Letters used in the study.....	96
	Appendix 3: Copies of letters and applications.....	97
	Appendix 4: List of tables and figures	99
	<i>List of tables.....</i>	99
	<i>List of figures.....</i>	99
	Appendix 5: Tables of raw data	100

Abstract

Background

Acupuncture is an ideal treatment alternative during pregnancy labour and birth as there are no severe side effects. Many studies report benefits of the use of acupuncture in actuating cervical ripening and spontaneous labour but its effectiveness needs to be assessed further.

Objective

This study serves as a pilot study for a future clinical trial that will evaluate the efficiency of acupuncture in actuating cervical ripening and spontaneous labour after 41 weeks (± 2 days) of normal pregnancy.

Methods

Healthy nulliparous women at 41 weeks (± 2 days) with a singleton normal pregnancy were randomized to either an acupuncture or control group. The control group received no treatment. The acupuncture group received one or two sessions of treatment: the first treatment at 41 weeks (± 2 days) and the second at 41 weeks and 5 days (± 2 days), if they were not yet in spontaneous labour. Each acupuncture treatment consisted of four needles applied to the bilateral points Hegu (LI4) and Sanyinjiao (SP6). Cervical status was assessed using the modified Bishop score. The primary outcomes were: (1) the mean time from randomization to onset of the active phase of labour; (2) the incidences of medical inductions; and (3) ripening of the cervix from 41 weeks (± 2 days) to 41 weeks and 5 days (± 2 days). Secondary

outcomes included rates of Caesarean section, duration of labour and use of oxytocin during labour. As this was a pilot study, it was considered sufficient to have 16 participants in the study, eight in the acupuncture group and eight in the control group.

Results

Sixteen women were randomized and completed the study procedure. No statistical difference in primary or secondary outcome was noted.

Conclusion

As a pilot study, the sample size is small and no statistically significant results are presented. Data collection tools were reliable and no major practical difficulties were encountered. Some changes in the research plan for a future study are suggested. According to the study data, the intervention is probably of small effect size and therefore a large sample will be required to test the effectiveness of this intervention in a future clinical trial.

Keywords: Acupuncture, spontaneous labour, induction of labour, cervical ripening.

1. Aims and purposes of the study

1.1 Introduction

It is something of an anomaly that it is necessary to disturb a normal physiological process by medical interventions such as induction of post-term labour, but there is strong evidence supporting this intervention as longitudinal epidemiological studies suggest increased risk of perinatal death by increasing gestational age after term. Many studies, both retrospective and prospective, indicate that induction of labour in nulliparous women increases the risk of Caesarean section (Glantz, 2005; Maslow and Sweeny, 2000; Vahratian et al, 2005; Vrouenraets et al, 2005). A Cochrane Review from 2006 demonstrated no significant difference in Caesarean delivery rates with a policy of induction of labour after term (Gülmezoglu et al, 2006), thus the evidence about Caesarean rate in relation to induction of labour in nulliparous women seems to be uncertain. The risk of Caesarean section in relation to induction of labour in nulliparous women appears to be greater when the Bishop score is unfavourable at the time of induction (Vrouenraets et al, 2005). It is a fact that elective induction of labour increased in-hospital pre-delivery time (Glantz, 2005; Maslow and Sweeny, 2000) and cost (Maslow and Sweeny, 2000). Even though induction of labour after 41 completed weeks of normal pregnancy is no longer associated with an increased rate of Caesarean section (Gülmezoglu et al, 2006) many women are concerned about having labour medically induced and are searching for natural ways to encourage labour to start. Acupuncture supports the natural process of giving birth and, according to several studies, its use is promising in reducing the incidence of medical inductions by actuating cervical ripening and

spontaneous labour. According to Gülmezoglu et al (2006), gestational age and cervical ripening may affect success in inducing labour and the resulting Caesarean section rates. If acupuncture can actuate cervical ripening then it may perhaps improve success rates in inducing labour, as the state of the cervix is the most important predictor of successful induction (Summers, 1997; Tenore, 2003). If acupuncture can actuate spontaneous labour, it may perhaps reduce the incidence of medical inductions.

It is important that midwives study complementary therapies and remedies to ensure adequate knowledge in order to guide women correctly and be able to offer complementary therapies in a safe way. It is also important to study the effectiveness of complementary therapies. Midwives should definitely be involved in conducting studies and promoting progress in this field as complementary therapies are certainly in the spirit of midwifery and can promote natural process.

Therefore, the purpose of this project is to conduct a pilot study for a future clinical trial. This pilot study will not have the power to test any of the hypotheses stated for the clinical trial or provide any statistically significant results. The purpose is, however, to make sure that the data collection tools are reliable and to detect any practical difficulties in following the intended method. The data from this pilot study will be a helpful precursor for future research employing a clinical trial.

1.2 Background

1.2.1 Acupuncture

Acupuncture has its origin in traditional Chinese medicine (TCM) (Yelland, 2005). According to Chinese medicine, human life is empowered by a basic life force of *chi* or vital energy that flows through the body in a network of pathways called meridians. There are 14 main meridians in the human body, all of which have acupuncture points along their pathways. In Chinese medicine, health is represented as a balance of yin and yang. The yin-yang theory is the core theory in Chinese philosophy and symbolizes the idea of the existence of two opposite aspects within all natural phenomena (Betts, 2006). The human body yin-yang theory is generally applied to the idea that well-being and health is a reflection of harmony of yin and yang, while sickness is a disharmony of yin and yang. TCM practitioners try to determine the exact nature of the imbalance, and then correct it through the use of appropriate intervention, such as herbal remedies, acupuncture, exercise, diet or lifestyle. Acupuncture treatment can intervene in the imbalance of the flow of *chi* and can be helpful in regaining balance. Acupuncture treatment involves placing thin sterile needles into acupuncture points and manually twirling them until the *de chi* effect is obtained (Skilnand et al, 2002; Tsuei et al, 1977; Yip et al, 1976). *De chi* is when a feeling of numbness, tingling and warmth is achieved (Skilnand et al, 2002) and means that *chi* is coming (Carlsson and Anckers, 1997).

The use of acupuncture has increased in Western medical practice and there is increasing evidence to support its use in relation to childbirth. Midwives and obstetricians are becoming more interested in using complementary therapies to reduce medical induction rates (Tiran, 2006). Acupuncture is complementary rather than adversative to Western medicine (Ewies and Olah, 2002) and goes well with midwifery. According to some commentators, acupuncture is ideal for childbirth as it is a drug-free intervention and has no harmful teratogenic effects, and women may be more willing to receive this kind of treatment (Ewies and Olah, 2002).

Acupuncture is safe when performed by an expert (Ernst et al, 2003) and side effects are relatively mild and infrequent (Cardini, 2004; Ernst et al, 2003; Smith and Crowther, 2004; Smith et al, 2002). Acupuncture can be used for both inducing labour (Kubista et al, 1975; Ledergerber, 1976; Tsuei and Lai, 1974; Tsuei et al, 1977; Yip et al, 1976; Dörr, 1990) and inhibiting labour (Tsuei et al, 1977). Pre-labour acupuncture can lead to a considerably improved ripening of the cervix (Gaudernack et al, 2006; Rabl et al, 2001; Romer et al, 2000; Tempfer et al, 1998; Tremeau et al, 1992; Zeisler et al, 1998) and has been used to treat many ailments of pregnancy, such as nausea, carpal tunnel syndrome, headaches, backache, oedema, varicose veins, haemorrhoids and constipation, to mention but a few (Ewies and Olah, 2002). Acupuncture can be effective for pain relief in labour (WHO, 2002; Skilnand et al, 2002) and can reduce its duration (Gaudernack et al, 2006; Kubista and Kucera, 1974a; Zeisler et al, 1998; Skilnand et al, 2002; Tempfer et al, 1998; WHO, 2002;). A recent systematic review and meta-analysis concluded that acupuncture given with

embryo transfer in women undergoing *in vitro* fertilization improved rates of pregnancy and live birth (Manheimer et al, 2008).

1.2.2 The researcher's experience in the use of acupuncture and the use of acupuncture at Landspítali University Hospital

The first acupuncture course for midwives in Iceland was offered in 2002. Following that course, the Directorate of Health in Iceland approved that midwives certified in acupuncture could provide acupuncture treatment during pregnancy, labour, delivery and in the post-partum period. There was great excitement about this innovation among practicing midwives and the demand for this skill was much higher than expected, resulting in a long waiting list for the courses. In 2003, as a newly graduated midwife, I had the opportunity to participate in an acupuncture course. Since then I have been offering acupuncture to women in my care on the labour and delivery wards at Landspítali University Hospital, where I practice. The midwives who participated in the first course were very efficient in putting acupuncture into practice on the labour and delivery wards at Landspítali University Hospital. After gaining the necessary approvals, they started to offer acupuncture to women in labour, mostly as a pain relief. The word spread quickly and, very soon, women started to ask for acupuncture as pain relief during labour. This demand resulted in pressure on other midwives to learn the skills of acupuncture to be able to fulfil women's requests. Today, the majority of midwives who take care of women during labour and birth at Landspítali University Hospital are able to offer acupuncture. According to a

summation of acupuncture use at Landspítali University Hospital for the period January 1 to April 30 2004, acupuncture was most often used as a remedy for labour pain (81.5%), for actuating relaxation in labour (73%) and to stimulate uterine contractions (10.5%) (Runarsdóttir, 2004).

Learning the skills of acupuncture requires extensive training; therefore, there is an excellent opportunity to study the effectiveness of acupuncture at Landspítali University Hospital. As the midwives are not familiar with stimulating needles with electricity, it is not a part of this study.

1.2.3 Beginning of labour and the mechanism of action of acupuncture on labour

The precise mechanism of the onset of labour in humans is still not completely understood but many complex biochemical and hormonal systems are involved. It is known that prior to labour cortisol levels increase in fetal plasma, oestrogen levels increase in the amniotic fluid and maternal plasma, and that prostaglandins play an important role in the onset of parturition (Lockwood, 2004). To a certain extent this is supported by the fact that disruption of the fetal hypothalamic–pituitary–adrenal (HPA) axis, e.g. in cases of anencephaly, or disruption of the synthesis of oestrogen, e.g. in placental sulphatase deficiency, can lead to prolonged gestation (Lockwood, 2004). The fetus provides an important signal for the initiation of parturition through increased secretion of pulmonary surfactant into the amniotic fluid during late

gestation (Mendelson and Condon, 2005). Oestrogen influences myometrial cell activity by increasing oxytocin receptors (Cluett, 2000), but oxytocin levels probably remain the same (Lockwood, 2004). Oxytocin activates the phospholipase C-inositol pathway and increases intracellular calcium levels, stimulating contractions in the smooth muscles of the myometrium (Tenore, 2003). Oestrogen also influences myometrial activity by stimulating prostaglandin production in the placenta and membranes, and possibly influences prostaglandin receptors in the cervix and the uterus which facilitate contraction coordination through the formation of gap junctions (Cluett, 2000). When the number of gap junctions increases it facilitates communication between cells in the myometrium and efficient transmission of contractions (Lockwood, 2004). Prostaglandins are associated with the onset of labour, possibly due to a reduction in natural prostaglandin-inhibiting substance (Cluett, 2000). Prostaglandins promote labour by augmenting the synthesis of matrix metalloproteinases (MMPs) in the fetal membranes and cervix and by increasing cervical expression of interleukin (IL)-8, which recruits and activates neutrophils and releases additional MMPs (Lockwood, 2004). During pregnancy, the cervix remains firm and non-compliant but these actions directly promote cervical change with or without membrane rupture. The crucial role of prostaglandins is supported by the fact that prostaglandin synthesis inhibitors delay parturition, whereas administration of prostaglandins initiate parturition (Lockwood, 2004).

The normal uterus is spontaneously contractile owing to individual cell activity but progesterone secreted from the placenta exerts a powerful inhibitory effect upon its

activity during pregnancy. Progesterone clearly contributes to the overall environment of labour but its role in labour is not yet clear (Cluett, 2000). In most pregnant mammals, uterine quiescence ends and labour starts when circulating progesterone decreases. This is in contrast to humans, in whom, levels of progesterone in maternal plasma do not decline prior to the onset of labour but the numbers of progesterone receptors in the uterus are elevated (Mendelson and Condon, 2005).

A rise of maternal serum levels of corticotrophin-releasing hormone (CRH) in the last few weeks of pregnancy appears to play a key role in fetal maturation and initiating labour after 33 weeks gestation as CRH-binding protein levels drop (Wadhwa et al, 2004). When CRH reaches the anterior pituitary gland, the pituitary is triggered into production of the adrenocorticotropin hormone (ACTH) which travels to the fetal adrenal cortex. Evidence also suggests that the initiation of parturition might be associated with an intrauterine inflammatory response as increased levels of interleukins in amniotic fluid and infiltration of neutrophils and macrophages in the myometrium have been associated with pre-term and term labour (Mendelson and Condon, 2005).

According to TCM, labour is expected to begin when three factors occur simultaneously: yang activity replaces yin material growth, *chi* flows freely and moves blood and the door of the uterus opens (Betts, 2006). These are fascinating

explanations that may explain the mechanism of action of acupuncture on labour induction, cervical ripening and duration of labour in the context of TCM; however, in Western medicine, objective explanations for this mechanism are sought. There are some theories about this mechanism although there are few studies in the literature that can be cited. It is thought that acupuncture may encourage the release of prostaglandins and oxytocin (Tenore, 2003) and is believed to stimulate the release of β -endorphins (Yelland, 2005), substances known to increase during labour helping the mother to cope with pain and create a sense of well-being. Beta-endorphin and ACTH both derive from the same precursor, pro-opiomelanocortin, so when there is a release of β -endorphins from the hypothalamus there is also a release of ACTH, an important substance in initiating labour (Curtis et al, 2006). Tempfer et al (1998) measured the serum levels of IL-8, prostaglandin ($\text{PGF}_{2\alpha}$) and β -endorphin in women who received prenatal acupuncture treatment to explain the effect of acupuncture and length of labour on the serum levels of substances active in ripening and dilating the cervix. Interestingly, the results indicated that acupuncture-related effects on cervical dilation and labour are not mediated by any greater release of β -endorphin, IL-8 or $\text{PGF}_{2\alpha}$. They speculate that the acupuncture treatment may increase uterine contractility either by parasympathetic stimulation of the uterus or by central oxytocin release. Zeisler et al (2000) evaluated the effect of prenatal acupuncture on serum levels of prostaglandin E_2 (PGE_2) during labour. They compared 40 primiparous women who received prenatal acupuncture with 40 primiparous women who did not. The serum levels of PGE_2 were measured at the end of the first stage of labour and the duration of the first and second stage were noted. Prenatal acupuncture was associated with increased serum levels of PGE_2 at the end of the first stage of labour

and with a shorter duration of the first stage. The authors proposed that prenatal acupuncture acting through peripheral sensory pathways mediated higher levels of PGE₂ and increased cervical dilatation. Dörr (1990) suggested that acupuncture stimulates the release of prostaglandins and cortisol from the fetus and oxytocin from the mother, thereby activating labour.

It appears that little is known about the underlying mechanism by which acupuncture might affect the onset of labour. Perhaps there are multiple mechanisms of actions of acupuncture in relation to initiation of labour, and prostaglandins probably have an important role. This might be studied further by measuring biochemical substances known to be involved in labour.

1.2.4 Post-term pregnancy

The World Health Organization defines a post-term pregnancy as a pregnancy of 42 completed weeks (294 days) or more. According to the College of Midwives of British Columbia (2003), 27% of pregnancies go beyond 41 weeks but the incidence of post-term pregnancy is 4–14%, averaging about 10% (Siozos and Stanley, 2005). The broad variation is a result of different definitions, induction policies and proportion of women with pregnancies of uncertain dates (Siozos and Stanley, 2005). According to these data, it can be estimated that the probability rate of spontaneous labour between 41 and 42 weeks is 48.2–85.2%.

The cause of post-term pregnancy is still unknown, but there is some evidence that a placental oestrogen deficiency may be a possible cause although the reason for the oestrogen deficiency is unknown (Gilbert and Harmon, 1998).

Post-term pregnancy is an appropriate indication for induction of labour as perinatal mortality and morbidity increase in otherwise normal pregnancies that continue past 42 weeks (Summers, 1997). The appropriate time to recommend delivery in normal pregnancy is controversial (Sanchez-Ramos et al, 2003). In developed countries, currently there are policies of induction of labour, often between 40 and 42 weeks gestation, or policies of expectant management, offering increased surveillance. Landspítali University Hospital has offered women increased surveillance when pregnancy has reached 41 weeks, and induction of labour at 41 weeks and 5 days to 42 weeks, but as the evidence base for optimal fetal surveillance in post-term pregnancies is limited this policy is, therefore, now under consideration.

1.2.5 Natural methods to induce or accelerate labour

Natural methods allow women greater control over the process of attempting to induce labour. These are methods expected to make a natural process start but not necessarily to induce it. It is appropriate to discuss natural methods, other than acupuncture, as the use of these methods might influence the outcome of this study.

All these methods have either been used in an attempt to actuate labour when there are non-urgent reasons for induction or to augment spontaneous labour, but are not used as a formal method of induction when there are urgent indications for induction.

1.2.5.1 Sweeping of membranes

Sweeping of membranes, also named stripping of the membranes, is a natural method that has received some attention in the literature and the evidence suggests that sweeping of membranes promotes the onset of labour at term (Boulvain et al, 2006). According to Boulvain et al (2006), there is little justification for routine sweeping of membranes for women near term in an uncomplicated pregnancy. However, it could be reasonable for women thought to require non-urgent induction as the intervention can promote the onset of labour by increasing local production of prostaglandins and, thus, reduce frequency of formal induction of labour. Sweeping of membranes is probably safe as long as there are no contraindications for vaginal birth although women often experience discomfort during and following the procedure, such as irregular painful contractions and bleeding (Boulvain et al, 2006).

1.2.5.2 Nipple stimulation

Many believe that regular nipple stimulation from 39 weeks of pregnancy reduces the likelihood of prolonged pregnancy. There is certainly a reasonable physiology behind this belief as it can release oxytocin from the posterior pituitary gland (Cooke, 1997),

but the evidence does not support it, as randomized trials have not shown any reduction in prolonged pregnancies (Siozos and Stanley, 2005).

1.2.5.3 Sexual intercourse

It is common for midwives to advise couples to make love as a means to ripen the cervix and induce labour, as there is a reasonable physiology behind the theory. According to Kavanagh et al (2001), no studies have confirmed its effectiveness and therefore the role of sexual intercourse as a method of induction of labour is unclear. Almost certainly there is a relationship between female orgasm and the release of oxytocin, and seminal fluid is known to be a concentrated source of prostaglandins (Cooke, 1997; Kavanagh et al, 2001). Lovemaking often includes stimulation of the breasts, which can also release oxytocin, as discussed earlier. As sex is considered safe during healthy pregnancy and does not increase the risk of premature birth, other factors such as a signal from the fetus must accompany sexual intercourse before it can have an effect on cervical ripening or uterine contractions.

1.2.5.4 Castor oil

Castor oil is widely used to initiate labour but the literature contains few references about its effectiveness. Castor oil can increase uterine activity as it involves the production of prostaglandins. One study showed that women who received castor oil had a greater chance of starting labour within 24 hours compared with women in the control group who received no treatment (Garry et al, 2000). One hundred women

with singleton pregnancies and membranes intact at 40 to 42 weeks participated in the study. Fifty-two women received castor oil and 48 were assigned to no treatment. After receiving castor oil, 30 of 52 women (57.7%) began in active labour but only 2 of 48 (4.2%) in the control group. In the study the Caesarean section rate was greater in the castor oil group (19.2%) than in the control group (8.3%), but was not significantly different. All the women in the castor oil group felt nauseous after ingesting the oil but no other adverse outcome was detected. Even though the sample in the study was small, the effect appears to be substantial.

1.3 Research objectives and hypotheses

The goal of a future clinical trial is to find out whether acupuncture can be effective in facilitating cervical ripening and actuating spontaneous labour in nulliparous women after 41 weeks (± 2 days) of normal pregnancy. Three hypotheses will be stated:

- 1. The mean time from randomization to onset of the active phase of labour is shorter in the research group than in the control group.**
- 2. The incidences of medical inductions are fewer in the research group than in the control group.**
- 3. The ripening of the cervix is greater in the research group than in the control group.**

2 Literature Review

2.1 Search strategy

A literature search was conducted in December 2006 using the search words 'acupuncture', 'uterine stimulation', 'induction of labour', 'ripening of cervix', 'initiation of labour' and 'augmentation'. The databases www.scopus.com, PubMed, CHINAHL and MIDIRS were searched. PubMed MESH database was also searched, using the MeSH terms 'Acupuncture' AND 'Labor, Induced', 'Acupuncture' AND 'Cervical Ripening' and 'Acupuncture' AND 'Uterine Contraction'. Owing to the repetition of papers in different databases, the result was 30 relevant papers. Unfortunately, five of the papers are written in Italian or German, languages that the researcher is unable to understand. The National Library of Medicine was searched for books in this field using the search words 'acupuncture in midwifery'. The search resulted in five books, two of which were relevant. At the time when the search was conducted, a subscription was made to new search or search alerts in the databases providing that service. Three papers were extracted via this subscription, one issued late in December 2006 (Gaudernack et al, 2006), one in April 2007 (Harper et al, 2006) and one in October 2007 (Selmer-Olsen et al, 2007). Additional papers were obtained through cross-referencing the literature cited in individual studies and reviews.

Studies reporting effects of acupuncture on induction of labour, duration of labour, cervical ripening and augmentation of labour are included in this review. Studies in a foreign language with no English abstract were excluded. Letters, commentaries and

reviews were also excluded, apart from the Cochrane Review (Smith and Crowther, 2004) and a review from WHO (2002), citing three Chinese studies.

There are 22 studies, two reviews and two books cited in this literature review. It includes discussion of 15 studies on acupuncture and induction of labour, five studies and one review on the influence of pre-labour acupuncture on duration of labour and two studies about acupuncture to accelerate labour. These are the core themes of the review. Furthermore, there is a discussion on acupuncture points, citing one book, one review and three studies that are also discussed elsewhere in this review.

2.2 Acupuncture and induction of labour

Acupuncture has been used for induction and augmentation of labour in China for centuries, with good success (Yelland, 2005). Several studies concerning acupuncture and induction of labour appear in the literature. The oldest study discussed here was published in 1975 and the newest in 2007. Unfortunately, small sample size seems to be a characteristic of most of these studies, which makes it almost impossible to draw any firm conclusions from the results, although all the studies report some benefit from the acupuncture treatment and no adverse effects. The acupuncture treatments in these studies were given at different gestational ages but none of the studies included only women after 41 weeks of pregnancy, as in this study. Different acupuncture points were used, and sometimes the acupuncture

treatment was standardized and other times individualized. Individualized treatment makes comparison between different studies difficult but is more in the spirit of Chinese medicine, where health and well-being is related to the balance of yin and yang. Hegu (LI4) and Sanyinjiao (SP6), which according to ancient Chinese medical literature are in charge of the function of the reproductive tract, were the acupuncture points most often used in these studies (Tsuei et al, 1977). The duration and frequency of treatments varied and different methods of needle stimulation were used. A summary of these studies is shown in Table 1 and further discussion appears below the table.

Table 2.1: Summary of studies about acupuncture and induction of labour

Citation Country of origin	Purpose	Method: - Research design - Sample - Measures	Intervention	Results	Strength Weakness Statistical tests
(Kubista et al, 1975) Austria	Evaluate whether electro-acupuncture can initiate contractions.	R: Matched control group. S: N=70 women with membranes intact. N=35 in AG, 22 primiparous, 13 multiparous. N=35 in CG. M: <ul style="list-style-type: none"> • Number of successful amniotomies. • Number of spontaneous deliveries. • Time from treatment to contractions. • Frequency, strength and length of contractions. • Apgar scores. 	AG Needles inserted in the points Jiaoxin (KI8), Zusanli (ST36) and 'Bachmann 25' bilaterally. One needle in Qihai (CV6). Electrically stimulated. Average total length of treatment was 2 h. CG No intervention.	The acupuncture treatment made the artificial rupture of membranes possible in 31 women who all delivered spontaneously. No latent period was observed.	S: Clearly defined and standardized treatment. W: No randomization. No intervention for control group. Small sample size. St: t-test
(Ledergerber, 1976) USA	Evaluate whether labour at term and pre-term could be induced by electro-stimulation and/or electro-stimulated acupuncture.	R: Case series S: N=17. N=12 at term, N=7 multiparas, N=5 nulliparas. N=5 pre-term. M: <ul style="list-style-type: none"> • Number of successful induction. • Induction time 	The acupuncture points Zhongji (CV3) and Da Heng (SP15) were electro-stimulated every 3 min for 15 sec, followed by electro-acupuncture if unsuccessful.	All the women at term were successfully induced and 3 of the 5 pre-term women.	S: Clearly defined and standardized treatment. W: No control group. Small sample size. St: Not documented.
(Yip et al, 1976) Hong Kong	Evaluate whether labour could be induced by electro-stimulated acupuncture.	R: Case series. S: 31 women either in post-term pregnancy or had mild pre-eclampsia (38–42 weeks). 20 primiparous, 11 multiparous. M: <ul style="list-style-type: none"> • Bishop score before stimulation. • Number of successful inductions. 	Needles inserted in the points Hegu (LI4) and Sanyinjiao (SP6) electrically-stimulated. Treatment continued throughout the 1st stage of labour.	In all but one, uterine contractions were initiated. Labour was successfully induced in 21 of the 31 women, 16 delivered spontaneously and 5 by vacuum extraction. No serious fetal or	S: Clearly defined and standardized treatment. W: No control group. Small sample size. St: Not documented.

Table 2.1: Summary of studies about acupuncture and induction of labour					
Citation	Purpose	Method: - Research design - Sample - Measures	Intervention	Results	Strength Weakness Statistical tests
		<ul style="list-style-type: none"> Maternal and fetal complications. Time from stimulation to the onset of contractions and to birth. 		maternal complications occurred. The pattern of uterine contractions resembles that of normal labour.	
(Tsuei et al, 1977) Taiwan and USA	<p>Evaluate whether labour could be induced by electro-stimulated acupuncture at term, post-term and midterm.</p> <p>Evaluate whether premature labour could be arrested by electro-stimulated acupuncture.</p>	<p>R: Case series. S: N=60. N=34, induction of labour at term or post-term. N=7, induction of labour in cases of intrauterine death. N=7, induction for labour in midterm pregnancy (15–23 weeks). N=12 inhibition of premature labour. M:</p> <ul style="list-style-type: none"> Bishop score before acupuncture treatment. Number of successfully induced contractions Induction–delivery time Treatment time Effect on uterine contraction Number of arrested premature labours. 	<p>Induction of labour Needles inserted in the points Hegu (LI4) and Sanyinjiao (SP6) bilaterally. Manual rotation in two cases but electrical stimulation in other cases. Treatment time 10 h 20 min to 24 h. For cases of midterm labour induction two alternative loci were used on the second day of treatment. Treatment time from 15 h, 30 min to 24 h.</p> <p>Arrest of labour Needles inserted in the points Kun-Sun (SP4) bilaterally. Electrically stimulated. Treatment time 4–16 h.</p>	<p>Induction of labour 78% success rate for labour induction at term, post-term and in case of intrauterine fetal death. All 7 cases who were induced for labour in midterm pregnancy failed to respond.</p> <p>Arrest of labour All but 1 women carried the pregnancy to term (36–42 weeks), 92% success rate.</p>	<p>S: Clearly defined and standardized treatment. W: No control group. Small sample size. St: Correlation matrix</p>
Dörr, 1990) Czechoslovakia.	Evaluate whether labour could be induced using electro-acupuncture in woman in which membranes had been disrupted	<p>R: Case series. S: N=16. Women with disrupted membranes of various parity M:</p> <ul style="list-style-type: none"> Number of spontaneous deliveries. Duration of labour. Time from the application of electrical acupuncture to the onset of contraction. Additional outcomes at birth. 	Hegu (LI4), Sanyinjiao (SP6) and Zusanli (ST36) in addition to auricular points. Four women also were pierced in Zhiyin (BL67). All bilaterally. Sanyinjiao (SP6) was stimulated electrically but other points were not stimulated.	Of the 16 women, 13 delivered spontaneously after the application of electrical acupuncture. No negative side effects were noted.	W: Not completely standardized treatment. No control group. Small sample size. St: Not documented.
(Tempfer et al, 1998) Austria	To measure levels of IL-8, PGF2 α and β -endorphin in women who received acupuncture treatment in late pregnancy and in controls to	<p>R: Matched Pair study. S: N=80 women, N=40 in the acupuncture group, N=40 in the control group. No information about proportion of nulliparous versus multiparous participants. M:</p> <ul style="list-style-type: none"> Duration of first and 	<p>Acupuncture treatment once a week from 35th week gestation.</p> <p>All women in the study group received acupuncture in the same four points</p>	<p>Significantly shorter duration of labour in the AG compared with CG (p<0.001)</p> <p>Acupuncture-related effects on cervical dilation and labour are not mediated by any greater release</p>	<p>S: Standardized treatment. W: Selection into groups not randomized. Small sample size. No blinding. St:</p>

Table 2.1: Summary of studies about acupuncture and induction of labour					
Citation	Purpose	Method: - Research design - Sample - Measures	Intervention	Results	Strength Weakness Statistical tests
	explain the effect of acupuncture and length of labour on the serum levels of substances active in ripening and dilating the cervix.	<p>second stage of labour.</p> <ul style="list-style-type: none"> • Serum levels of IL-8. • Serum levels of PGF_{2α}. • Serum levels of β-endorphin. • PROM • Use of analgesics, oxytocins and epidural anaesthesia. • Frequency of episiotomy, perineal tear and vaginal laceration. 	<p>i.e. Bai Hui (GV20), Shen Men (HE7) and Nei Guan (PC6).</p> <p>Treatment lasted for 20 min.</p> <p>Needles stimulated manually.</p>	<p>of IL-8 and PGF_{2α}.</p> <p>No significant difference between other birth-related outcomes measured in the study</p>	<p>Kendall tau-b correlation coefficient.</p> <p>Paired t-test.</p> <p>McNemar test.</p> <p>Two sided test.</p> <p>P values smaller than 0.05 were considered statistically significant.</p>
(Rabl et al, 2001) Austria	Evaluate whether acupuncture at term can influence cervical ripening and thus reduce the need for induction of post-term pregnancies.	<p>R: Single blind randomized controlled trial</p> <p>S: N=45 women at term, N=25 in the AG, 23 nulliparous, 2 multiparous N=20 in CG, 17 nulliparous, 3 multiparous.</p> <p>M:</p> <ul style="list-style-type: none"> • Cervical length measured with vaginal ultrasonography. • Cervical mucus obtained for a fetal fibronectin • Time from first pos. fibronectin test to delivery. • Initial Bishop score • Time from EDD to the actual time of delivery. • Number of post-date inductions. • Duration of labour (first and second stage). • Proportion of women who needed oxytocin to augment labour. • Mode of delivery. 	<p>AG</p> <p>The points Heug (LI4) and Sanyinjiao (SP6) were pierced every second day from estimated day of delivery (EDD).</p> <p>Neutral needle technique.</p> <p>Treatment lasted for 20 min.</p> <p>No needle stimulation.</p> <p>CG</p> <p>No intervention.</p>	<p>Acupuncture shortened the interval from EDD to the actual time of delivery (p=0.03) and led to quicker ripening of the cervix (p=0.04).</p> <p>No significant difference between other birth-related outcomes measured in the study.</p>	<p>S: RCT</p> <p>Clearly defined and standardized treatment.</p> <p>W: No intervention for control group. Small sample size.</p> <p>St: Wilcoxon's test.</p> <p>Fisher's exact test.</p> <p>t-test.</p> <p>Chi-square test.</p> <p>P values smaller than 0.05 were considered statistically significant.</p>
(Harper et al, 2006) USA	Evaluate the benefit of outpatient acupuncture for labour stimulation in nulliparous women.	<p>R: Randomized controlled trial</p> <p>S: N=56 nulliparous women 39 4/7 weeks or greater, 30 in the acupuncture group, 26 in the control group.</p> <p>M:</p> <ul style="list-style-type: none"> • Time from randomization to delivery. • Mode of delivery. • Frequency of spontaneous labour. • Neonatal complications • Change in Bishop score. 	<p>AG</p> <p>All received the same four points i.e. Hegu (LI4), Sanyinjiao (SP6), Shangliao (BL31) and Ciliao (BL32). BL31 and BL32 were stimulated electrically but others were not stimulated.</p> <p>Treatment lasted for 30 min.</p> <p>Treatments administered three times (on three out of four consecutive days).</p> <p>CG</p> <p>No intervention.</p>	<p>The results showed no difference in Bishop scores between the groups but the mean time to delivery was 21 h less in the acupuncture group; however this did not reach statistical significance.</p>	<p>S: RCT</p> <p>W: Small sample size. Absence of masking healthcare providers. No intervention for control group.</p> <p>St: Student's t-test</p> <p>Chi-square analysis</p> <p>Two-sided p-values less than or equal to 0.05 were considered statistically significant.</p> <p>Kaplan–Meier test.</p>
(Gaudernack et al, 2006)	Evaluate if acupuncture could be a	<p>R: RCT</p> <p>S: N= 100 healthy women with spontaneous rupture of</p>	<p>AG</p> <p>All received the same three points</p>	<p>Not significant difference between the numbers who</p>	<p>S: RCT</p> <p>Standardized and</p>

Table 2.1: Summary of studies about acupuncture and induction of labour

Citation Country of origin	Purpose	Method: - Research design - Sample - Measures	Intervention	Results	Strength Weakness Statistical tests
Norway	reasonable option for augmentation of labour following pre-labour rupture of membranes at term. Evaluate possible effects on the progress of labour.	membranes at term. N=48 in AG, 25 nulliparous, 23 multiparous. N=52 in CG, 27 nulliparous, 25 multiparous. M: <ul style="list-style-type: none"> • Duration of active phase of labour. • Oxytocin > 2 h • Oxytocin < 2 h • Time from PROM to birth • Number of inductions • Use of prostaglandin • Additional outcomes at birth. 	i.e. Zusanli (ST36), Taichong (LIV3) and Guanyuan (CV4). Additionally, individual treatment based on pulse and tongue diagnose and principles of traditional Chinese medicine. Only one treatment that lasted for 20 min. No stimulation of needles. CG No intervention.	needed medical induction. Not significant difference between time from PROM to birth. Significantly shorter duration of labour in AG (p=0.027). Significantly shorter active phase of labour in AG when labour was induced (p=0.002). Significantly less need for oxytocin to augment labour in AG (p=0.018). No adverse effects.	individualized treatment. W: Small sample size. No intervention for control group. St: Chi-square test Student's t distribution Mann-Whitney U-test P-values calculated based on the log-rank test. Pearson's or Spearman's correlation.
(Selmer-Olsen et al, 2007) Norway	Evaluate if acupuncture influences the onset of labour and the need for induction after pre-labour rupture of membranes. Also to investigate a possible effect of acupuncture on the woman's well-being.	R: RCT S: N=106 nulliparous women with PROM. N=51 in AG, 55 in CG. M: <ul style="list-style-type: none"> • Time from PROM to onset of active phase of labour • Rate of inductions. • Women's well-being • Additional outcomes at birth. 	AG The point Guanyuan (CV4) was used for all. Choice of other acupuncture points was based on traditional Chinese medicine, using questionnaire on symptoms, tongue and pulse diagnosis. Treatment lasted for 30 min. Additional treatment offered the day after if the women were still not in labour. Needles stimulated manually. CG No intervention.	No significant effect in reducing time to active labour or in reducing induction rate. No change in well-being as a result of acupuncture.	S: RCT Standardized and individualized treatment. W: Small sample size. No intervention for control group. St: Kaplan-Meier plots. Log-rank test. Exponential distribution regression model. Pearson's χ^2 Agresti-Caffo CI. ANCOVA Student's t-test Pearson's χ^2 Two-sided p-values <0.05 were considered statistically significant.

AG=Acupuncture group, CG=Control group

Kubista et al (1975) carried out a study on 35 women who all received electrical acupuncture as a method of initiating contractions. All 35 women experienced labour pains after only 20–25 minutes of stimulation and the acupuncture treatment made the artificial rupture of membranes possible in 31 women who all delivered spontaneously. The contractions did not stop when the stimulation with acupuncture ended and no latent period was observed. This is important as membrane rupture without uterine contractions poses the possibility of ascendant infection. The authors conclude that because there is often a long latent period after the rupture of membranes, and that can increase fetal jeopardy, preparatory treatment with electro-acupuncture could be beneficial.

Ledergerber (1976) was 100% successful in inducing labour using electro-stimulation and/or electro-acupuncture in 12 women at term. Three of five pre-term women were successfully induced. This study is interesting as the author evaluated and confirmed the uterine stimulation effect of electric current applied to specific acupuncture points by measuring the pressure in the amniotic fluid. He indicated that the closer the points were to the uterus, the more powerful the stimulation. According to his results, Sanyinjiao (SP6) is a good uterine stimulator but several other acupuncture points, such as Zhongji (CV3) and Da Heng (SP15), the points used in his study, are more powerful.

Yip et al (1976) conducted a study using electrical acupuncture for induction of labour. The 31 women included in the study were either in post-term pregnancy or had mild pre-eclampsia. Yip et al (1976) used the same acupuncture points as Tsuei et al (1977) based on the concept in TCM that certain acupuncture loci should be avoided in pregnancy as stimulation of these points may cause abortion or premature labour by inducing uterine contractions. Uterine contractions were induced in all but one case, and labour was successfully induced in 21 of the 31 women: 16 delivered spontaneously and five by vacuum extraction (Yip et al, 1976).

A study by Tsuei et al (1977) included 60 pregnant women, of whom 34 were at term or post-term. The acupuncture technique used in this study was based on ancient Chinese medical literature that considers the acupuncture points Hegu (LI4) and Sanyinjiao (SP6) to be in charge of the function of the reproductive tract. Manual rotation of the acupuncture needles was used in only two cases and electrical stimulation in the remainder. The treatment time varied from 2 hours and 55 minutes to 15 hours and 50 minutes. Of the 34 women at term and post-term pregnancy, 29 successfully went into labour. Owing to disproportion, four of the 29 delivered by Caesarean section. In the five unsuccessful cases, contractions were successfully induced, but the cervix failed to open.

The studies discussed above from the 1970s (Kubista et al, 1975; Ledergerber, 1976; Tsuei et al, 1977; Yip et al, 1976;) all report great success in inducing labour

using electro-acupuncture. None of these studies were randomized controlled trials but the results suggest a strong effect of the intervention. Even though these studies are not recent and it is not the goal of this study to assess the effectiveness of electro-acupuncture, their results are important as in two of the studies (Yip et al, 1976; Tsuei et al, 1977) Hegu (LI4) and Sanyinjiao (SP6) were used, the same acupuncture points as employed in this study.

Dörr (1990) evaluated whether labour could be successfully induced using electro-acupuncture in women in whom membranes had been disrupted. Of 16 women in the study, 13 were successfully induced with electro-acupuncture and delivered spontaneously. No adverse outcomes were noted. The sample size in this study is small and there is no control group, but there seems to be a strong effect of this intervention similar to the studies from the 1970s.

Tempfer et al (1998) conducted a matched control study and reported the beneficial effect of acupuncture on the duration of labour. In their study, 40 women who received acupuncture once a week from the 35th week of pregnancy had a significantly shorter duration of labour, compared with 40 women who did not receive acupuncture. Interestingly, the acupuncture points used in this study are used for relaxation and sedation and can be helpful in cases of insomnia and nausea but are not known to stimulate uterine contractions (Carlsson & Anckers, 1997). The results

of this study may, therefore, support the benefits of relaxation as a preparation for labour.

Rabl et al (2001) conducted a single-blind randomized controlled trial in Austria to evaluate whether acupuncture at term can influence cervical ripening and thus reduce the need for induction of post-term pregnancies. Their results indicated that treatment with acupuncture shortens the interval from the estimated day of delivery to the actual delivery and leads to quicker ripening of the cervix. The sample size in this study is probably too small to draw any conclusions from the result. However, it is correctly designed to evaluate the effectiveness of a clinical intervention and was the only study included in the Cochrane Review on acupuncture for induction of labour (Smith and Crowther, 2004), where it is suggested that acupuncture can stimulate the onset of labour and aid cervical ripening.

Harper et al (2006) conducted a randomized controlled trial of acupuncture in North Carolina, USA for the initiation of labour in nulliparous women. Two acupuncture points were stimulated electrically but others were not stimulated. The results showed no difference in Bishop scores from the day of enrolment to the day of admission for delivery between the groups but the mean time to delivery was 21 hours less in the acupuncture group; however, this did not reach statistical significance. The authors concluded that acupuncture was well tolerated among nulliparous women at term and may be effective in reducing interventions that occur

in post-term pregnancies. The sample size was small, only 30 in the acupuncture group and 26 in the control group.

Gaudernack et al (2006) conducted a study in Norway in which they investigated whether acupuncture could be a reasonable option for augmentation of labour following the pre-labour rupture of membranes at term (PROM). They also looked for possible effects on the progress of labour. The difference between the numbers who needed medical induction was not significant, nor the time from PROM to birth, but women who received acupuncture had a significantly shorter duration of labour and needed significantly less oxytocin to augment labour. In this study, acupuncture points believed to be important for women with PROM were chosen. The sample size was probably too small as there were only 25 nulliparous and 23 multiparous women in the acupuncture group and 27 nulliparous and 25 multiparous women in the control group.

2.3 Influence of pre-labour acupuncture on duration of labour

Evidence suggests that pre-labour acupuncture can reduce the duration of labour. Several studies report benefits such as cervical maturation and shorter duration of labour resulting from pre-labour acupuncture (Gaudernack et al, 2006; Kubista and Kucera, 1974a; Romer et al, 2000; Tempfer et al, 1998; Tremeau et al, 1992; Zeisler et al, 1998), but results from Lyrenäs et al (1987) demonstrated the opposite, i.e. lengthened pregnancy and duration of second stage of labour.

Kubista and Kucera (1974a) undertook a matched control group study in Austria. The control group consisted of 60 primiparous women who received no treatment. The acupuncture group consisted of 60 primiparous women who received acupuncture once a week before their due date. Each session lasted 20–25 minutes and the majority underwent three treatments. The acupuncture points selected for this study, Zusanli (ST36), Jiaoxin (KI8), Yanglingquan (GB34) and Shenmai (BL62), are all points that are often used as pre-birth points (Betts, 2006). The results showed that the average subjective duration of labour, defined by the onset of the first regular pains in intervals of 10–15 minutes, was significantly shorter ($p < 0.02$) in the acupuncture group but there was no significant difference of the duration of the active phase of labour, defined as beginning with a cervical dilation of 3–4 cm.

Zeisler et al (1998) reported similar results in a matched control study from Austria. They included 120 primiparous women, 57 in the acupuncture group and 63 in the control group. Each acupuncture treatment lasted for 20 minutes and was given once a week from the 36th week of gestation. The acupuncture points used in this study, Bai Hui (GV20), Shen Men (HE7) and Nei Guan (P6), are known to be effective in sedating and relaxing. Women in the acupuncture group had a significantly shorter duration of the first stage of labour ($p < 0.0001$), received significantly less oxytocin during the first ($p = 0.01$) and second stages ($p = 0.03$) of labour compared with women in the control group. There was also a significantly increased frequency of PROM ($p = 0.02$) in the acupuncture group. Similar to the

results of Tempfer et al (1998), this study may also support the benefits of relaxation as a preparation for labour.

In a study from Sweden, acupuncture treatment was given once a week from the 36th week of gestation until delivery and each session lasted for 30 minutes (Lyrenäs et al, 1987). Most of the women received more than three treatments, with a mean of five treatments. The acupuncture points selected for this study, Zusanli (ST36), Sanyinjiao (SP6), Yanglingquan (GB34) and Shenmai (BL62), are effective in sedation and relaxation as well as energizing the pelvic organs. The sample consisted of 56 primiparous women who volunteered in the acupuncture group and a selected control group of 112 primiparous women. It is worth mentioning that as a requirement for participation in the acupuncture group, women had to consent to having two lumbar punctures, one during pregnancy and one post-partum. This requirement may have affected the range of women who agreed to receive acupuncture. The results showed no significant difference in the duration of labour between the two groups, but the authors stated that there was a significantly longer duration of labour in the acupuncture group as significantly fewer women in this group delivered within an hour of the second stage and the second stage of labour exceeded 2.5 hours in a significantly higher number of women ($p < 0.05$). Length of gestation was significantly longer in the acupuncture group ($p < 0.001$). It is noteworthy that the control group was twice as big as the acupuncture group and that there were significantly more smokers in the control group ($p < 0.05$). These dissimilarities of the two groups might well have affected the results, as smoking has

been linked to premature birth (Morgan et al, 2007). The range of gestation was 33–42 weeks in the control group but 35–42 in the acupuncture group, which might also have affected the results. These results conflict with the results from a German study from 1974 where significant reduction in delivery time were found in primiparous women who received similar treatment in late pregnancy (Kubista and Kucera, 1974b cited in Lyrenäs et al, 1987).

Tremeau et al (1992) reported significantly more progression of the Bishop score in the acupuncture group compared with a control group who received no treatment and a placebo group. Acupuncture sessions were carried out at the beginning of the ninth month of pregnancy, using acupuncture points that are known to stimulate uterine contractions. This study was conducted in France, hence the article is written in French and only the abstract is available in English. In my opinion, it is inappropriate to give acupuncture using points with known uterine stimulating effects prior to term as it may cause premature labour.

Romer et al (2000) reported that prenatal acupuncture caused morphologic changes at the cervix prior to delivery and that uterine contractions appeared to be better coordinated in women who received specific prenatal acupuncture, leading to more efficient and shorter labour. In this study, 878 primiparous women in Germany were recruited, 329 women with uncomplicated pregnancies received specific acupuncture treatment once a week from 36 weeks gestation until delivery. A control group of 325

women who received no treatment and another control group of 224 women received non-specific (placebo) acupuncture. The acupuncture points Zusanli (ST36), Yanglingquan (GB34), Sanyinjiao (SP6) and Zhiyin (BL67), all known to promote labour or prepare labour, were used for the specific acupuncture group in this study (Betts, 2006). Interestingly, the acupuncture points used for the placebo group in this study were the sedating and relaxing points Baihui (GV20), Neiguan (PC6) and Shenmen (HE7). These same points were used in the study of Zeisler et al (1998), who reported very positive results from the use of pre-labour acupuncture. Unfortunately, this article is written in German so only the abstract written in English is available. This seems to be a well-designed study with an adequate sample size and, therefore, firm conclusions can be drawn from the results, which are very positive regarding the use of pre-labour acupuncture. It would be interesting to conduct a similar study but beginning the acupuncture a week later, as I believe it is inappropriate to give acupuncture using points that are known to have a uterine stimulating effect when the gestation is only 36 weeks as it may cause premature labour.

2.4 Acupuncture to accelerate labour

Acupuncture may be effective in reducing the time of active labour, either by accelerating slow processing labour (Pei-chong, 1998) or perhaps by reducing the need for epidural analgesia in labour (Skilnand et al, 2002).

Pei-chong (1998) reported effectiveness in accelerating slow processing labour in 49 (79%) of 62 cases by puncturing Sanyinjiao (SP6) and Hegu (LI4) bilaterally and retaining the needles for 30 minutes. In this study, the average speed of cervical dilation increased significantly after acupuncture as well as the intensity and frequency of contractions. As there was no control group it is difficult to draw any conclusions from the results.

Skilnand et al (2002) looked at the effects of acupuncture for pain relief in labour and possible effects on the progress of labour in a controlled, single-blind study. Two hundred and ten healthy women in spontaneous active labour at term were randomly assigned to a true acupuncture group or false acupuncture group. There were significantly lower pain scores and significantly less need for pharmacological analgesia in the true acupuncture group compared with the control group and the women in the true acupuncture group spent less time in active labour and needed less augmentation than women in the control group. The authors believe that the shortening effect of the true acupuncture on delivery time was mainly a consequence of reduced need for epidural anaesthesia, which is known to slow down the process of labour. Their conclusion is interesting but is not supported by Gaudernack et al's study (2006) in which the women who received acupuncture had a significantly shorter duration of labour and needed significantly less oxytocin to augment labour than the control group although there was not a significant difference of epidural use in that study.

2.5 Acupuncture points

Sanyinjiao (SP6) is used in most of the studies discussed in this literature review, most frequently with Hegu (LI4) but sometimes with other acupuncture points. Sanyinjiao (SP6) is considered to improve circulation in the lower abdomen (Rabl et al, 2001) and according to the ancient Chinese literature, Sanyinjiao (SP6) is considered to be the main point for induction of labour (Betts, 2006; Tsuei and Lai, 1974). Hegu (LI4) is believed to have a great energetic and oxytocic effect (Rabl et al, 2001) and is considered as an auxiliary point for induction of labour (Betts, 2006; Tsuei and Lai, 1974). WHO (2002), citing three Chinese studies reported that certain points, such as Hegu (LI4), Sanyinjiao (SP6) and Zhiyin (BL67) may cause miscarriage but are useful if induction of labour is desired and that the effect is comparable with that of oxytocin by intravenous drip. According to Ledergerber, (1976) Sanyinjiao (SP6) is a good uterine stimulator although several other acupuncture points may be even more powerful.

2.6 Gaps in the knowledge

The evidence certainly suggest some benefits of the use of acupuncture in induction of labour, cervical ripening, augmentation of labour and duration of labour but there is still a huge gap in the knowledge as inappropriate study designs and small sample sizes make it difficult to draw firm conclusions from most of the studies. The pre-labour acupuncture treatment used in Romer et al's study (2000) appears to be effective in ripening the cervix and shortening labour in nulliparous women. The study by Rabl et al (2001) suggested that pre-labour acupuncture treatment shortens

the interval from the estimated day of delivery to the actual delivery and leads to quicker ripening of the cervix although this needs to be studied further in a trial with a larger sample. Acupuncture is a clinical intervention and therefore its effectiveness needs to be assessed in well-designed clinical trials with adequate sample sizes. It will be the project of future clinical trials to discover the most appropriate combination of acupuncture points and whether to give standardized or individual treatment, or a combination of both. It will, moreover, be the project of future clinical trials to discover when the time is ideal to begin pre-labour acupuncture treatment, the optimal frequencies of treatments, duration of each treatment and the optimal interval between each treatment.

3 Methodology

3.1 Research approach

This study is a pilot study for a randomized clinical trial comparing acupuncture with no treatment. Pilot studies are small-scale tests carried out in preparation for a major study to ensure that the data collection tool is reliable and that there are no unforeseen or unanticipated practical difficulties in following the intended method (Rees, 2003). A future clinical trial may possibly answer the question of whether acupuncture is effective in facilitating cervical ripening and spontaneous labour after 41 weeks (± 2 days) in nulliparous women in normal pregnancy. Clinical trials are useful to test the effectiveness and safety of a particular intervention (Polit and Beck, 2006; Rees, 2003), and random allocation ensures that everyone in the trial has the same chance of ending up in either group (Rees, 2003).

3.2 Inclusion and exclusion criteria

Those eligible for the research were healthy nulliparous women having normal pregnancies, carrying one fetus alive and with no contraindications for vaginal birth. The pregnancy length should be 41 weeks (± 2 days) at randomization. If women showed any signs of being in labour or if they had ruptured membranes they were excluded. Labour was considered to be starting if contractions, lasting more than 30 seconds, were occurring at least every 10 minutes. There are few contraindications for acupuncture and therefore women were excluded from the study if any of the following were present: use of thromboprophylaxis medicine, nickel or metal allergy,

any signs of infection at the acupuncture sites, any underlying disease such as bleeding disorders, heart diseases, renal diseases, hepatitis or HIV (Carlsson and Anckers, 1997; Yelland, 2005).

As it is important that the estimated date of delivery (EDD) is reliable and calculated as accurately as possible, women were excluded from the study if there was any doubt about the length of the pregnancy.

3.3 Sample

As this is a pilot study, it was considered sufficient to recruit 16 participants to the study, eight in the acupuncture group and eight in the control group. This pilot study will make it possible to estimate sample size needed for a clinical trial.

According to the College of Midwives of British Columbia (2003), 27% of pregnancies continue until 41 weeks and, therefore, it was important to offer only women who were nearly 41 weeks into their pregnancy the opportunity to participate in the research, in order to minimize deletion from the sample. Almost 3,000 births per year take place at Landspitali University Hospital. Assuming that 27% of pregnancies will continue until 41 weeks and 75–80% of them will fulfil the criteria for the research, and that nulliparous women are approximately 45% of the population, then the population count is roughly 280 women per year.

3.4 Gaining ethical approval

When conducting studies involving humans, it is essential to adhere to basic human rights, i.e. respect for individual autonomy, protection from harm and justice (Rees, 2003). This research involves human participants and therefore it required research ethics approval. As the research was undertaken outside the UK, in Iceland, it required ethical approval from the local ethics review system as well as from the University's Research Ethics Committee (U-REC). In order to apply for ethical approval from the Icelandic National Bioethics Committee, a local supervisor, other than a student, was necessary. Helga Gottfreðsdóttir, a midwife and an assistant professor in the Faculty of Nursing at the University of Iceland took on this responsibility. The study gained full approval from the Icelandic National Bioethics Committee on the 19 February 2008 (Ref: VSNb2008010008/03-7) (see Appendix 3). The U-REC of the University of Sheffield reviewed and recognized the Icelandic National Bioethics Committee's procedure (see Appendix 3), therefore the approval from the Icelandic National Bioethics Committee was satisfactory. On 19 December 2007 the research was granted ethical approval for data collection from the office of Data Protection Authority in Iceland (see Appendix 3).

Midwives practising prenatal care in the Primary Health Care of the Capital Area introduced the study to women who fulfilled the study criteria when gestation had reached 40 weeks. The midwife briefly explained the study and if the woman was

interested she gave her an 'Introductory letter for prospective participants' (see Appendix 2) which contained further information about the study. Then the woman had to consent to the midwife informing the researcher of her name and phone number. Next, I contacted these women, gave further information about the study and answered questions. If they were still interested in participating in the study and if there were no contraindications to taking part, an appointment was made. On arrival, each woman was asked to sign an informed consent form thereby agreeing to participate in the study. The 'Letter of informed consent' (see Appendix 2) was in accordance with the requirements of the National Bioethics Committee. It included information about the purpose of the study, the identification of the researcher and the organization, the nature of the participation, possible risks or implications of participating and any anticipated benefits. It also ensured participants' confidentiality and informed them that there would be no need to participate, assured them that they had the right to withdraw at any time and, finally, offered the opportunity to ask questions.

To ensure confidentiality all the forms used for data collection in the study were labelled with unique identifiers to make sure that names could not be linked to the data.

3.5 Research process

On 28 February 2008, 37 midwives at all the health care centres of the Primary Health Care of the Capital Area in Iceland, a total of 17 health care centres, were prepared to introduced the study to healthy nulliparous women approaching 41 weeks of normal pregnancy. On 4 March, the first woman enrolled for the study and on 9 May, the last woman enrolled.

When women had provided their written consent, they were randomly allocated to the research group or the control group by selecting a sealed, opaque envelope on their arrival at 41 weeks. Twenty envelopes were prepared. Numbers from 1 to 20 had been previously randomized to the control and acupuncture group using computerized randomization in Excel. The acupuncture group had the numbers 1, 3, 5, 6, 13, 14, 15, 17, 18 and 20 and the control group 2, 4, 7, 8, 9, 10, 11, 12, 16 and 19. The envelopes included all the forms needed for the research (see Appendix 1), information about whether the woman was in the research group or the control group and numbered stickers to label the forms. The midwife who gave the acupuncture treatment filled in one form for each treatment. The midwife or the physician who performed the assessment of the cervix, filled in one form for each assessment at the time of the assessment. The midwife who took care of the women during labour and birth filled in one form regarding the birth outcomes.

After randomization, the paper indicating whether the women belonged to the acupuncture or control group was discarded. The women were also instructed not to state which group they belonged to on their return, apart from to the midwife who would take care of them during their visit at 41 weeks and 5 days as that midwife would be the one to give acupuncture if they belonged to the acupuncture group.

In clinical trials, it is important to describe the interventions in detail. Standards for reporting interventions in controlled trials of acupuncture, the STRICTA recommendations (MacPherson et al, 2001), are followed to describe the interventions in detail. The acupuncture treatment for the research group consisted of the insertion of four sterile, disposable 25×0.25 mm and 50×0.30 mm acupuncture needles from Cloud & Dragon. The needles were inserted bilaterally in the acupuncture points Hegu (LI4) at a depth of 1–2.5 cm (0.5–1 cun) and Sanyinjiao (SP6) at a depth of 2–4 cm (1–1.5 cun), until the *de chi* needling sensation was achieved. Needles were retained for approximately 20 minutes and were manually stimulated by twirling them 5, 10 and 15 minutes after insertion. The control group received no acupuncture.

The selection of acupuncture points and methods is based on the literature (Betts, 2006; Rabl et al, 2001; Tsuei and Lai, 1974; WHO, 2002). For convenience, the hospital's protocol on prolonged pregnancy influenced the timing and frequency of interventions. The researcher believes that this practical adjustment is theoretically

acceptable as there is no evidence suggesting the optimal frequencies of pre-labour acupuncture treatments or the optimal interval between treatments. According to the hospital's protocol for prolonged pregnancies, women are offered fetal surveillance and assessment of the cervix at 41 weeks and 5 days. This latter session of treatment and/or assessment was in relation to the visit to the hospital at 41 weeks and 5 days (± 2 days) but the first session of treatment and/or assessment at 41 weeks (± 2 days) was an additional visit to the hospital for the study's sake only.

At 41 weeks (± 2 days) a midwife in the prenatal outpatient care or a midwife at the delivery unit performed a vaginal examination, as it was necessary for the purpose of the study to establish a baseline for the modified Bishop score. After the examination, the researcher gave the acupuncture treatment if the participant was in the acupuncture group. At 41 weeks and 5 days (± 2 days) a midwife in the prenatal unit, or the researcher, gave the acupuncture while a cardiotocogram (CTG) was on, since CTG is a part of routine surveillance in post-term pregnancy at Landspítali University Hospital. At this point either a physician or midwife performed a vaginal examination, the purpose of which was to decide the method of induction of labour as an induction was pending at that time. Unfortunately, it was not possible to prevent the physicians or midwives who performed the vaginal examinations at 41 weeks and 5 days (± 2 days) from knowing whether the woman received acupuncture or not as the acupuncture treatment was given in a room that was relatively open and easily accessible to personnel. Therefore, there was no guarantee of the blindness of midwives or physicians involved in the study.

After birth, the midwife who delivered the baby filled in the form with information about outcomes related to the birth.

3.6 Concept definitions

3.6.1 Meridians

According to Chinese medicine, human life is empowered by a basic life force of *chi* or vital energy that flows through the body in a network of pathways called meridians. There are 14 main meridians, all of which have acupuncture points along their pathways. Twelve of the meridians are named according to zangfu, the 12 organs of Chinese medicine (Betts, 2006). The Zang refers to the five solid (yin) organs: liver (LI), heart (HE), spleen (SP), lung (LU) and kidney (KID), which store vital substances such as blood and body fluids. The Zang also refers to the pericardium (PC). The Fu refers to the six hollow (yang) organs: stomach (ST), small intestine (SI), large intestine (LI), gall bladder (GB), bladder (BL) and San Jiao (SJ), which assimilate valuable substances from food and descend and discharge the waste (Betts, 2006). The remaining two meridians, the Conception vessel (CV), often referred to as the Ren channel and the Governing vessel (GV), often referred to as the Dun channel belong to a group termed the eight extraordinary vessels.

3.6.2 Acupuncture points

There are 361 acupuncture points located along or near the meridians and many more are located off these meridians and are known as extra points. Each acupuncture point is named after the meridian it belongs to and the number of the point. Each point has a Chinese name as well, for example large intestines, number four is called Hegu (LI4). The two letters within the parentheses are the agreed alphabetic code for the 14 meridians according to Standard International Nomenclature (West, 2001). For the sake of consistency in this dissertation, acupuncture points are described by the Chinese name preceding the agreed alphabetic code within the parentheses, along with the number, for example, Hegu (LI4).

The acupuncture points Hegu (LI4) and Sanyinjiao (SP6) are frequently used in obstetrics and gynaecology and seem to be the acupuncture points most often used for induction of labour. Sanyinjiao (SP6) is located on the medial side of the lower leg, 3

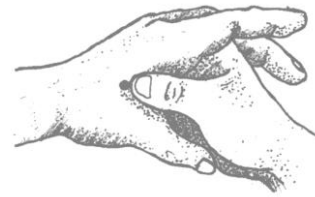
Figure 3.1: Sanyinjiao (SP6)



cun superior to the prominence of the medial malleolus, in a depression close to the medial crest of the tibia (see Figure 3.1). Sanyinjiao (SP6) is one of the pre-eminent acupuncture points. As its name implies it is the meeting point of the three yin channels of the leg, the spleen, the liver and the kidney meridians. The needle is inserted perpendicular 1–1.5 cun. Hegu (LI4) is located on the dorsum of the hand,

between the first and second metacarpal bones, at the midpoint of the second metacarpal bone and close to its radial border (see Figure 3.2). The needle is inserted perpendicular 0.5–1 cun. Hegu means union of the valley and is a yang point.

Figure 3.2: Hegu (LI4)



3.6.3 Cun

Cun is a traditional Chinese unit of length. One cun is the distance between a person's first and second joint on the middle finger or the width of their thumb at the knuckle (Carlsson and Anckers, 1997). The width of the two forefingers denote 1.5 cun and the width of four fingers side-by-side is 3 cun (Carlsson and Anckers, 1997). This unit of length was used to chart acupuncture points on the human body in various uses of traditional Chinese medicine (Wikipedia, the free encyclopedia, 2007).

3.6.4 Active phase of labour

Morrin (1997) describes the beginning of the first stage of labour as 'the onset of regular uterine contractions, accompanied by effacement of the cervix' (p. 355). In some studies, the onset of the active phase of labour is defined as when the cervix is dilated 3 cm and there are at least two contractions per 10 minutes (Selmer-Olsen et

al, 2007). In the delivery units at Landspítali University Hospital it is the custom to document the onset of the active phase of labour in the maternal record. The recorded time is an assessment commonly made by the midwife and the woman and sometimes her companion as well. A clear definition for the active phase of labour was not stated when midwives were taught how to fill in the form for the outcome of the birth. However, they were asked to write the same time as they wrote in the maternal record as the usual method used by the midwives is consistent with the definitions described above.

3.6.5 Cervical ripening

Cervical ripening is a physiological development whereby the cervix becomes softer, shorter and more pliable. Uterine contractions normally begin as the cervix begins to ripen and, ideally, both the cervix and the uterus are prepared for labour at the same time. It is difficult to separate the methods of cervical ripening and induction of labour, as when the cervix is unripe a stimulating method may facilitate its ripening, but when the cervix is ripe the same intervention might facilitate onset of labour (Summers, 1997). The state of the cervix is the most important predictor of successful induction, whereby ripening of the cervix facilitates labour and increases the chance of vaginal delivery (Gülmezoglu et al, 2006; Summers, 1997; Tenore, 2003).

3.6.6 The Bishop score and the modified Bishop score

In 1964, Edward H. Bishop presented a pelvic score system to make easier the selection of women most suitable for induction, a procedure that had become frequent and acceptable at that time (Bishop, 1964). His scoring system, referred to as the Bishop score, has served as a simple and standardized way of assessing the maturity of the cervix (Summers, 1997). The modified Bishop score was used in this study, as it is the custom to use that scoring system at Landspítali University Hospital. The modified Bishop score, often referred to as the Calder score, is slightly different from the original Bishop score as the cervical length in centimetres replaces the percentage of effacement and there is a difference in the scoring of the position of the cervix. In the modified Bishop score, each component is given a score of 0–2 or 0–3 and the total score ranges from 0 to 12 (see Table 3.1).

Table 3.1: Modified Bishop score				
	Score			
Cervical feature	0	1	2	3
Dilatation (cm)	<1	1–2	2–4	>4
Length of cervix (cm)	>4	2–4	1–2	<1
Station (cm)	–3	–2	–1/0	+1/+2
Consistency	Firm	Average	Soft	-
Position	Posterior	Mid; Anterior	-	-

If the score is <5 – the cervix is unfavourable, 5–8 – the cervix is moderately favourable and >8 – the cervix is very favourable (Medforth et al, 2006). The higher the initial score, the more successful is induction (Summers, 1997; Tenore, 2003).

3.6.7 Estimated date of delivery (EDD)

For women who are certain of their last normal menstruation it is simple to calculate accurately the EDD using Naegele's rule, but the most reliable calculation of EDD is when the day of conception is certain (Proud, 1997). According to Crowley (2006), the use of reliable early ultrasound in pregnancy can avoid unnecessary induction of labour owing to incorrect diagnosis of post-term pregnancy. As it is the custom in Iceland to use estimated date of delivery according to the ultrasound examination at 19–20 weeks gestation, it was appropriate to use that date in this study.

3.6.8 Induction of labour

When induction procedures are used to bring on labour that has not begun spontaneously, it is considered to be induction of labour. In the Western world, induction of labour is most often a procedure that involves the use of pharmacologic agents such as prostaglandins E₂, misoprostol E₁ or oxytocin, mechanical dilation of the cervix with balloon catheters or amniotomy. The preferred method is selected based on the ripening of the cervix and previous obstetric history.

There are many natural and non-invasive methods linked to labour induction and ripening of the cervix. Sweeping of the membranes, use of castor oil, herbs, homeopathic solutions, acupuncture, nipple stimulation, sexual intercourse and enemas are examples of these natural methods (Summers, 1997). These natural methods are usually not used to induce labour but are used in the hope of bringing

on labour when there are no hasty indications for induction of labour but when it is safe for the women and her baby to go into labour.

3.6.9 Spontaneous labour

Spontaneous labour is the onset of regular and painful contractions without the use of pharmacologic agents, mechanical dilation of the cervix with balloon catheters or amniotomy.

3.7 Data collection and analysis

Demographical information about race and age were collected as well as maternal information on gestational age and number of previous pregnancies (see Appendix 1: 'Demographical and maternal information'). The researcher collected these data and filled in this form. This information was important in comparing the two groups.

The midwife who gave the acupuncture treatment filled in one form for each treatment (see Appendix 1: '41 weeks (\pm 2 days)' and '41 weeks and 5 days (\pm 2 days)') and one form was filled in by the midwives and the physicians each time they assessed the cervix (see Appendix 1: 'Cervical ripening – modified Bishop score').

Acupuncture treatment is the independent variable. The main dependent variables are the time from randomization to the onset of the active phase of labour, numbers

of medical inductions and the changes in Bishop scores between the initial examination and the second examination. Outcomes related to labour and birth were also assessed. These include rates of Caesarean sections, rates of forceps and vacuum extraction deliveries, duration of the three stages of labour, the use of pain relief in labour, use of medication and amniotomies for inductions or augmentation in labour, maternal post-partum bleeding, Apgar scores and newborn admissions to an NICU (see Appendix 1: 'Assessment of outcome'). The midwives who attended the birth collected these data and filled in this form.

Boxes for completed forms were located on the wards where the research took place, from where the researcher collected them.

The data were originally entered into Microsoft Excel and then imported to SPSS, which was then used to analyse the data. Graphs were created in Excel. The independent samples t-test was used to compare the differences between the two groups in the case of continuous variables where mean could be calculated. A paired sample t-test was used to compare the difference between the initial modified Bishop score and the modified Bishop score at 41 weeks and 5 days (± 2 days). A chi-squared test was used to test statistical significance to assess whether a relationship exists between two nominal-level variables. For calculation of the relationship between the initial Bishop score and the time to active phase of labour Pearson's r correlation test was used.

4 Results

4.1 Demographic information

Sixteen nulliparous women were included in the study, eight in the acupuncture group and eight in the control group. The data from all women were evaluated. All the women were Caucasians and there were no differences in terms of age, modified Bishop score or gestation at the time of randomization (see Table 4.1). Membranes were swept in one case at 41 weeks (± 2 days) and in four cases at 41 weeks and 5 days (± 2 days), two in each group.

	Acupuncture group N=8	Control group N=8	P-value
Participant's age – mean value (SD)	28.1 (5.3)	28.78 (5.7)	0.82
Gestation (days) – mean value (SD)	286.6 (1.1)	286.6 (1.5)	1
Modified Bishop score – mean value (SD)	4.5 (1.3)	3.8 (2.2)	0.42
<i>Independent sample t-test</i>			

4.2 Flow of participants

None of the women in the acupuncture group went into labour immediately after acupuncture but one woman in the control group went into labour approximately 1 hour after randomization. Her membranes had been swept earlier that day. Seven women, four from the control group and three from the acupuncture group went into spontaneous labour before the second session of the study at 41 weeks and 5 days (± 2 days). Therefore, only four women from the control group were assessed at 41 weeks and 5 days (± 2 days) and five women from the acupuncture group received

the second acupuncture treatment and were assessed at that time. Of the total of 16 women, five in the control group went into spontaneous labour and four in the acupuncture group. Labour was therefore induced in three women in the control group but in four in the acupuncture group (see Figure 4.1).

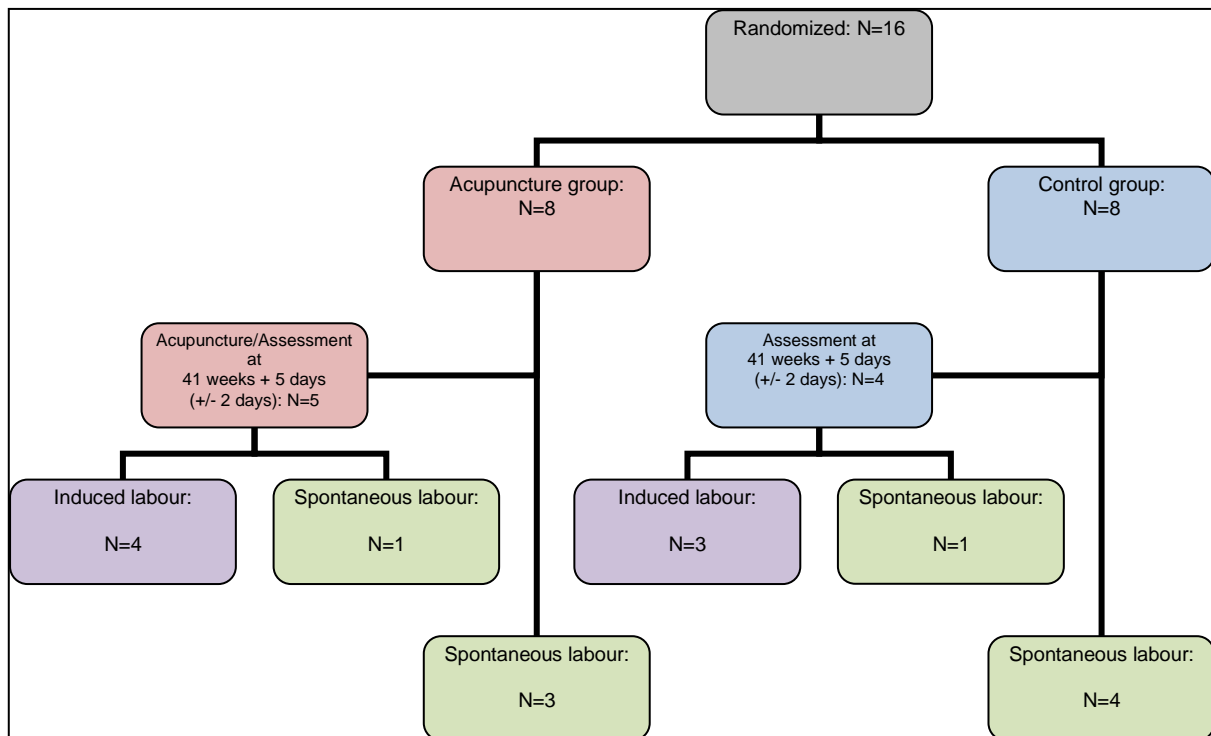


Figure 4.1: Flowchart of study participants

4.3 Time from randomization to the active phase of labour

The mean time from randomization to onset of the active phase of labour was shorter in the control group than in the acupuncture group, but the difference did not reach statistical significance ($p=0.18$, independent sample t-test, see Table 4.2).

Table 4.2: Time from randomization to the onset of the active stage of labour			
	Acupuncture group N=8	Control group N=8	P-value
Mean time from randomization to the onset of active stage of labour (SD)	8.48 minutes (4.626)	5.48 minutes (3.810)	0.18
	141:16 hours:min	91:24 hours:min	
<i>Independent sample t-test</i>			

4.4 Cervical ripening

The cervix was assessed at randomization and again at 41 weeks and 5 days (± 2 days) if women were not in labour at that time. As seven women went into labour before this time, information about the difference of the modified Bishop score was available from nine women. The cervical ripening from randomization to the second assessment was greater in the acupuncture group than in the control group but the difference did not reach statistical significance ($p=0.36$, independent samples t-test, see Table 4.3).

Table 4.3: Cervical ripening from randomization to second assessment at 41 weeks and 5 days			
	Acupuncture group N=5	Control group N=4	P-value
Difference of Bishop score – mean (SD)	1.80 (1.92)	0.75 (0.95)	0.36
<i>Independent sample t-test</i>			

The mean modified Bishop score at randomization was slightly higher in the group of women who went into spontaneous labour (4.43) before 41 weeks and 5 days than in the group who did not (3.89) but the difference did not reach statistical significance

($p=0.56$, independent samples t-test, see Table 4.4). There cervixes ripened significantly ($p=0.04$, paired t-test, see Table 4.4) from the time of randomization to 41 weeks and 5 days (± 2 days) in this group of nine women as the mean modified Bishop score was 3.89 (SD 1.8) at randomization but 5.22 (SD 2.2) at 41 weeks and 5 days (± 2 days) (see Table 4.4).

Table 4.4: Mean of modified Bishop score at randomization and at 41 weeks and 5 days (± 2 days)			
	Modified Bishop score at randomization	Modified Bishop score at 41 weeks and 5 days (± 2 days)	P-value
N=16 The whole sample – mean score (SD)	4.12 (1.8)	N/A	N/A
N=7 The group who went into spontaneous labour before 41 weeks and 5 days – mean score (SD)	4.43 (1.9)	N/A	N/A
N=9 The group that was available for second assessment at 41 weeks and 5 days (± 2 days) – mean score (SD)	3.89 (1.8)	5.22 (2.2)	0.04*
P-value	0.56**		
<i>*Paired sample t-test **Independent samples t-test</i>			

The relationship between the modified Bishop score at randomization and the time from randomization to the active phase of labour was investigated using Pearson product-moment correlation coefficient ($r=-0.30$, $N=16$, $p=0.9$). This is a medium correlation (Cohen 1988, cited in Pallant, 2007) but not statistically significant. As this is a negative correlation it suggests that time to the active phase of labour is shorter when the modified Bishop score is higher.

4.5 Incidences of medical inductions and spontaneous labour

The incidences of medical inductions were greater in the control group. This difference did not reach statistical difference (see Table 4.5). The phi coefficient value for these two nominal variables is 0.126, which is considered a small effect using Cohen's (1992) criteria for effect size. One woman in the control group went into labour approximately 1 hour after randomization. Her membranes had been swept earlier that day but she was the only woman to have membranes swept at that time. Membranes were swept in four women at 41 weeks and 5 days (± 2 days), two in each group. One woman in each group went into spontaneous labour therefore sweeping of membranes should not have affected the outcome apart from maybe this one in the control group who went into spontaneous labour soon after randomization, the same day as her membranes were swept.

	Acupuncture group N=8	Control group N=8	Total
Spontaneous labour	4	5	9
Induced labour	4	3	7
TOTAL	8	8	16
<i>P-value =0.61, Pearson chi-Square; phi value=0.126 (small effect size)</i>			

4.6 Duration of labour

The duration of labour was calculated for the women who delivered normally and with vacuum extraction but women who had Caesarean sections were excluded. First stage of labour, second stage of labour, third stage of labour and the overall duration of labour was longer in the acupuncture group but did not reach statistical significance (see Table 4.6).

	Acupuncture group N=6	Control group N=4	P-value
Duration of the first stage of labour – mean (SD)	806 minutes (267) 13:26 hours:min	583 minutes (108) 9:42 hours:min	0.16
Duration of the second stage of labour – mean (SD)	125 minutes (49) 2:05 hours:min	79 minutes (39) 1:19 hours:min	0.16
Duration of the third stage of labour – mean (SD)	15 minutes (16)	7 minutes (1)	0.33
TOTAL duration of labour	946 minutes (253) 15:46 hours:min	669 minutes (111) 11:08 hours:min	0.07
<i>Independent samples t-test</i>			

4.7 Mode of birth

The study showed that five women in the control group had instrumental deliveries in contrast to three women in the acupuncture group. The overall rate of normal births was 50%, the rate of Caesarean sections 37.5% and the rate of vacuum extractions 12.5%. In the control group, four women had Caesarean sections, one due to an unrecognized breech position and three for failure to progress. In the acupuncture group, two women had Caesarean sections, both for failure to progress. One woman in each group delivered via vacuum extraction because of prolonged second stage of labour. A significant difference between the two groups was not detected (see Table 4.7 and Figure 4.2). A calculation of Cramer's V value indicates a small effect size according to Cohen's (1992) criteria for effect size.

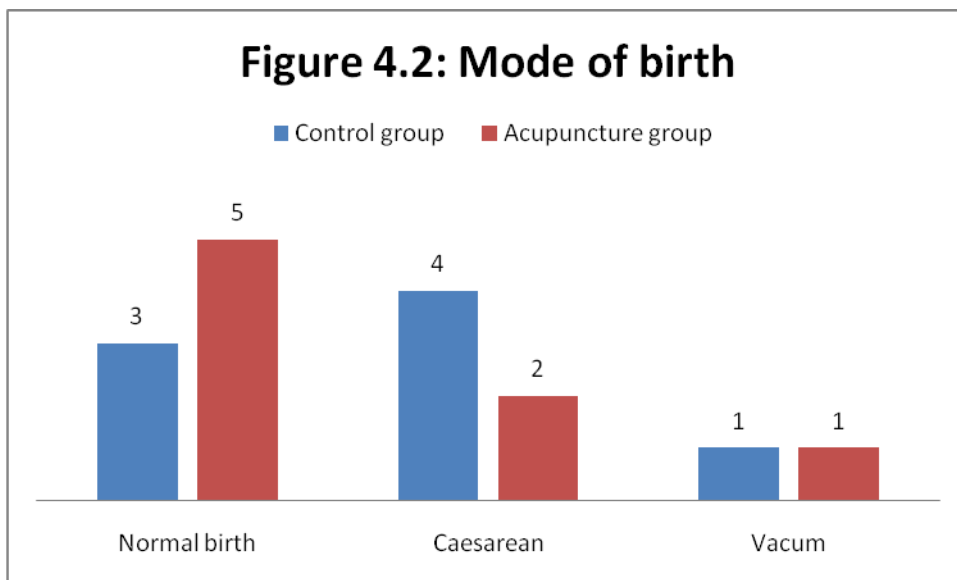


Table 4.7: Mode of birth			
	Normal birth	Caesarean section	Vacuum extraction
Acupuncture group N=8	5	2	1
% within group	62.5	25	12.5
% within mode of birth	62.5	33.3	50
% of total	31.2	12.5	6.2
Control group N=8	3	4	1
% within group	37.5	50	12.5
% within mode of birth	37.5	66.7	50
% of total	18.8	25	6.2
TOTAL	8	6	2
%	50	37.5	12.5

P-value=0.56, Pearson chi square; Cramer's V value=0.270 (effect size=small)

4.8 Use of pain relieving agents

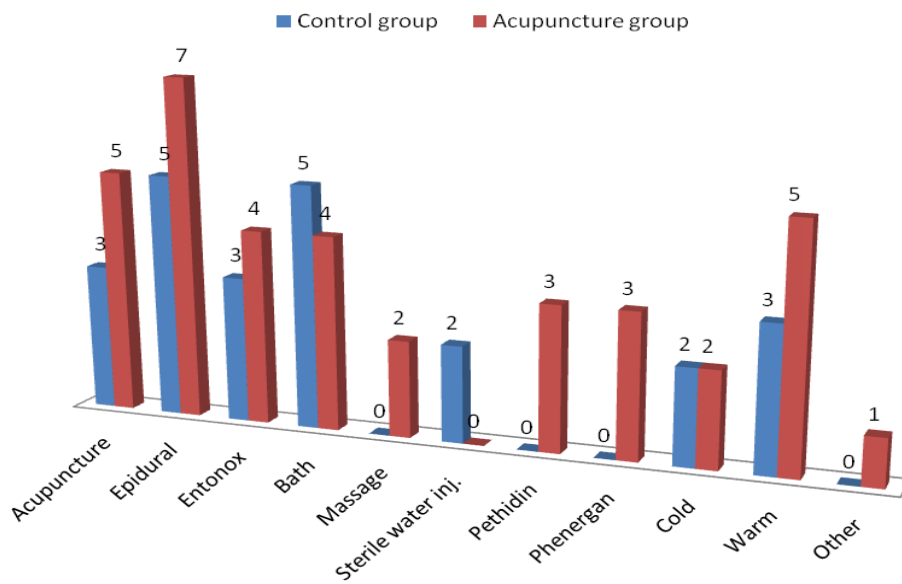
Overall, there was more use of pain relieving agents in the acupuncture group than in the control group; in particular, there was a greater use of pharmacological agents such as Pethidine, Phenergan, Epidural and Entonox (see Table 4.8 and Figure 4.3). This difference was not statistically different but the difference in the use of Pethidine and Phenergan was close to statistically different ($p=0.06$).

Table 4.8: Use of pain relieving agents

	Acupuncture group N=8	Control group N=8	P-value
Acupuncture	5	3	0.32
Epidural	7	5	0.25
Entonox	4	3	0.61
Bath	4	5	0.61
Massage	2	0	0.13
Sterile water injections	0	2	0.13
Pethidine	3	0	0.06
Phenergan	3	0	0.06
Cold	2	2	1
Warm	5	3	0.32
Other	1	0	0.30

Pearson chi square

Figure 4.3: Use of pain relief during labour



4.9 Need for pharmacological agents and amniotomies for augmentation and induction of labour

Only two women, one in each group, in whom labour started spontaneously finished labour without augmentation. All the other women who started spontaneously in labour required amniotomy, oxytocin or both (see Table 4.9).

Table 4.9: Use of amniotomies and oxytocin to augment spontaneous labour, N=9				
	Amniotomy but not oxytocin	Oxytocin but not amniotomy	Amniotomy and oxytocin	TOTAL
Acupuncture group N=4	1	0	2	3
Control group N=5	0	2	2	4
TOTAL	1	2	4	7

Four women in the acupuncture group and three from the control group needed conventional induction of labour with prostaglandins, oxytocin and/or amniotomy. Prostaglandins were used for induction in three cases in the acupuncture group and two cases in the control group. Labour was induced by oxytocin in one case in the control group because of the rupture of membranes before labour. Labour was induced by amniotomy in one case in the acupuncture group because of a favourable cervix. All the women who were induced needed oxytocin (see Table 4.10).

Table 4.10: Use of amniotomies and pharmacological agents to induce labour and augment induced labour, N=7

	Amniotomy but not oxytocin	Oxytocin but not amniotomy	Amniotomy and oxytocin	TOTAL
Acupuncture group N=4	0	0	4	4
Control group N=3	0	1	2	3
TOTAL	0	1	6	7

4.10 Post-partum blood loss

Post-partum blood loss was calculated for the women who delivered normally and with vacuum extraction but women who had Caesarean sections were excluded. A slightly greater blood loss was detected in the control group than in the acupuncture group but the difference did not reach statistical significance ($p=0.73$, independent samples t-test, see Table 4.11).

Table 4.11: Post-partum blood loss

	Acupuncture group N=6	Control group N=4	P-value
Post-partum blood loss ml – mean (SD)	567 (334)	763 (828)	0.61
<i>Independent samples t-test</i>			

4.11 Apgar score

There was no difference in Apgar scores of 1 minute and 5 minutes (see Table 4.12). One neonate recorded less than seven Apgar scores at 5 minutes but scored eight

at 10 minutes. This neonate belonged to the acupuncture group. He was admitted to the neonatal intensive care unit (NICU) and recovered quickly. One neonate from the control group was admitted to the NICU due to maternal pyrexia and also recovered quickly.

Table 4.12: Apgar scores			
	Acupuncture group N=8	Control group N=8	P-value
Apgar score 1 minute – mean	7.88	7.75	0.89
Apgar score 5 minues – mean	9.25	9.12	0.86
<i>Independent samples t-test</i>			

5 Analysis and Discussion

5.1 Primary outcomes

5.1.1 Hypotheses

This study serves as a pilot study therefore the sample size is small, and for that reason, no statistically significant results are presented. The purpose of a pilot study is to test the methods of the proposed study including participant recruitment, administration of treatment, acceptability of treatment, power calculations and data collection. For the same reason none of the three hypotheses that will be stated in a future clinical trial are supported or rejected at this time. The results indicate a negative trend for the first two hypotheses and a positive trend for the third one.

1. The mean time from randomization to onset of the active phase of labour was longer in the research group than in the control group but the first hypothesis states the opposite.
2. The incidences of medical inductions were greater in the research group than in the control group but the second hypothesis states the opposite.
3. The ripening of the cervix was greater in the research group than in the control group as stated in the third hypothesis.

Even though there is no statistical difference in any of the primary outcomes, the results are important for a future clinical trial. The results contribute in calculating appropriate sample size and can be helpful for defining what should be considered a significant difference in single variables. Taking into account the data from this pilot study and using the effect-size indexes and conventional values from Cohen (1992), a sample size of 392 women in each group is required in a future clinical trial to have 80% power and a significance level of 5% as the effect size of this intervention is likely to be small. A high (48.2–85.2%) probability rate of spontaneous labour between 41 and 42 weeks gestation, as discussed earlier, also contributes to the need for a large sample.

5.1.2 Cervical ripening

The mean modified Bishop score at randomization was slightly higher in the group of women who went into spontaneous labour before 41 weeks and 5 days than in the group of women who did not, but the difference did not reach statistical significance. This is consistent with Bishop's work (1964) which suggested that the time to spontaneous onset of labour is in direct relation to the pelvic score. In this group of nine women who were not in labour at 41 weeks and 5 days (\pm days) the cervix ripened statistically significant from the time at randomization to 41 weeks and 5 days (\pm 2 days). The mean modified Bishop score was 3.89 at randomization but 5.22 at 41 weeks and 5 days (\pm 2 days) a mean change of 1.33 points. This difference was greater in the acupuncture group (1.80) than in the control group

(0.75) but did not reach statistical significance. These figures are important in the discussion of what should be considered as a significant change in the modified Bishop score. My clinical experience suggests that a change in the score of 3 would definitely be considered clinically significant as there is a great difference between 6 and 9 or 4 and 7, for example. In one study where two different medical interventions for cervical ripening were compared (Pollnow and Broekhuizen, 1996), a change in the score of 3 was thought to be clinically significant because that change resulted in a 'ripe' cervix as the mean initial Bishop score was 4 in each group, which is similar to the findings in this study. According to guidelines from the RCOG (2001), nulliparous women with a modified Bishop's score of less than 4 receive a different dosage of prostaglandin gel than other women, thus a change in the score of 1 or 2 points can slightly differ the method of induction but is not necessarily clinically significant. If the score is <5 – the cervix is unfavourable, 5–8 – the cervix is moderately favourable and >8 – the cervix is very favourable (Medforth et al, 2006). Usually more prostaglandin is required to ripen an unfavourable cervix than a moderately favourable cervix, and when the cervix is very favourable prostaglandin is not required but an amniotomy can be done. The difference between an unfavourable to a very favourable cervix can be 5 or more points but a change in 3 points is a change of category and therefore a different clinical intervention is required. A change of 3 points in the modified Bishop score is, therefore, clinically and statistically significant.

5.2 Secondary outcomes

Even though there is no statistical difference in any of the secondary outcomes, there are some relevant and interesting results regarding high rates of instrumental births, use of pain relieving agents and the use of pharmacological agents and amniotomies for augmentation of labour.

5.2.1 Mode of birth

The rates of instrumental births are very high in this study when compared to figures from Iceland in 2006. The rates for Caesarean sections were 37.5% and vacuum extractions 12.5%. In Iceland, the overall rate of vacuum deliveries is 6.5% and the overall Caesarean rate is now 17.5%, thereof 11% are emergency Caesarean sections (Landspítali University Hospital, 2007). With such a small sample it is inappropriate to discuss percentages as only two cases contribute to 12.5% vacuum deliveries but it may provide an idea of the outcome. One Caesarean section was due to an unrecognized breech position and if that case is excluded the Caesarean section rate goes down to 33.3%, which is still very high.

5.2.2 Use of pain relieving agents

Three women in the study (18.8%) received Pethidine and Phenergan as a pain relieving agent. All three women were in the acupuncture group so the difference between the two groups was close to being statistically different ($p=0.06$). This is

striking, as these medications are not without side effects for the baby as they cross the placenta. Pethidine is not often given as a pain relieving agent in the active phase labour at Landspítali University Hospital but is sometimes used for pain relief along with Phenergan during a difficult latent phase of labour. Unfortunately, no numbers on the use of Pethidine and Phenergan are available from Landspítali University Hospital but numbers are available from a smaller hospital in Iceland – the hospital in Akureyri – where epidural analgesia is available 24 hours a day similar to Landspítali University Hospital. In 2006, 7.6% of women in the hospital in Akureyri received Pethidine during labour (Landspítali University Hospital, 2007). The use of opiates for the relief of pain during labour has decreased because of the growing popularity of epidural analgesia (Medforth et al, 2006) and none of the recent studies cited in the literature review apart from Skilnand et al (2002) comment on the use of Pethidine, but many report the use of epidural analgesia. In the study by Skilnand et al (2002) where the effectiveness of acupuncture as a pain relieving method was assessed, there was significantly less use of Pethidine in the acupuncture group ($p < 0.001$). In the study by Tempfer et al (1998) the need for analgesics and epidural analgesia was neither reduced nor increased by pre-labour acupuncture treatment. It is possible that pre-labour acupuncture may result in a longer or more difficult latent phase, therefore it is important to define and document the length of time of that phase of labour and monitor the use of opiates carefully in future studies. In the study of Kubista et al (1975) where electro-acupuncture was used as a method of initiating contractions no latent period was observed, and Kubista and Kucera (1974a) reported a significantly shorter latent phase in the acupuncture group that received acupuncture once a week before the due date.

Twelve women (75%) in the study received epidurals as pain relief for labour, which is high compared with figures from two hospitals in Iceland. At Landspítali University Hospital, 34% of all labouring women, both primiparous and multiparous, received epidurals during labour 2006 and 53.9% of primiparous women at The Hospital in Akureyri (Landspítali University Hospital, 2007).

5.2.3 Need for pharmacological agents and amniotomies for augmentation and induction of labour

There is a very high rate of labour augmentations even in the cases of spontaneous labour as only one woman in each group managed to finish labour without augmentation with amniotomy or oxytocin, or both. What is striking is that there is not a policy of active management of labour at this hospital but these figures suggest a trend in that direction. Also, many women in the study received epidural analgesia. High rates of epidurals and augmentations might be linked as the use of epidural often calls for augmentation and augmentation often calls for an epidural. At any rate, the two women in this study who did not need any augmentation did not receive an epidural either.

5.2.4 Post-partum blood loss

The mean post-partum blood loss was calculated for the 10 women who delivered normally and with vacuum extraction. Usually, blood loss of more than 500 ml is considered significant and the definition of major haemorrhage is blood loss of more than 1,000 ml (Medforth et al, 2006). The mean post-partum blood loss was more than 500 ml in both groups: 567 ml in the acupuncture group and 763 ml in the control group. These high means are the result of small numbers, including two cases of major haemorrhage as one women in the acupuncture group lost 1,200 ml and one in the control group 2,000 ml. When the cases of major haemorrhage are excluded, the mean post-partum blood loss is 350 ml in the control group and 440 ml in the acupuncture group.

5.3 Methodology

5.3.1 Tools of data collection and data collection

Data collection appears to be reliable but instructions about filling in the forms requires improvement, as there are many professionals involved. An example of this is the need in writing for a clear definition on the beginning of the active phase of labour. Even though it is difficult to define accurately the beginning of the active phase of labour it is important to have a written definition included in the instructions on how to fill in the outcome forms. If this had been the case it would probably have increased the quality of the study.

In a future clinical trial, it may be appropriate to describe the characteristics of the study groups in more detail and in order to do that more detailed demographical and maternal information needs to be gathered. This will enable a more precise comparison of the two groups and may be helpful in providing further explanations of the outcomes:

- Information about smoking habits is appropriate as smoking during pregnancy may affect gestation length and other outcomes (Secker-Walker & Vacekb, 2003).
- Information about body mass index (BMI) at the beginning of pregnancy and weight gain during pregnancy are also appropriate as Caesarean section rates increase in correspondence with increased BMI (Weiss et al, 2004).
- It would be interesting to document birth weight as such information may shed light on other variables such as instrumental deliveries.

During data collection and analysis ideas about more comprehensive documentation of secondary outcomes arose:

- It would be important to document the time and date when induction of labour begins in order to calculate the time from the beginning of induction to the active phase of labour to see whether pre-labour acupuncture has any effects on that.

- It would also be interesting to document for how long oxytocin is used, if used for augmentation, to be able to differentiate between short-term use and long-term use.
- Documentation about the colour of the amniotic fluid is interesting and may well be relevant. This idea originated from a midwife who uses acupuncture frequently as she believes that there is more frequently meconium-stained amniotic fluid when acupuncture is used for augmentation of labour.
- As it is possible that pre-labour acupuncture may result in a longer or more difficult latent phase it is important therefore to define and document the time of the latent phase of labour and continue to document the use of opiates in future studies.

5.3.2 The interventions

Consideration was given to whether the control group should receive no treatment or sham acupuncture, but the researcher believes that it is acceptable in this research to give no treatment to the control group. The main rationale for this decision is that comparison of results with other studies might be difficult or even impossible. The control groups in the most recent research in this field have received 'no treatment' (Gaudernack et al, 2006; Harper et al, 2006; Rabl et al, 2001; Tempfer et al, 1998). Kubiena (1989), who looked at 28 controlled studies using 28 different acupuncture placebos, reported that comparison of results were impossible because of this and states that 'a genuine acupuncture placebo is as unthinkable as placebo-surgery' (p. 362). The stimulation that may arise with sham acupuncture might produce a small

effect that could compromise comparison with the research group. By using no treatment instead of placebo acupuncture, it is impossible to blind the women from knowing whether they are in the research group or the control group. For the purpose of this study, the researcher believes that it is not a great disadvantage as even though aware of the group they are in the participants will not be able to have an effect on the dependent variables.

Many of the women who participated in the study seemed to be stressed, anxious and nervous. Therefore, it would have been desirable to be able to give them relaxing acupuncture treatment in addition to the standard treatment and this should be considered in a future clinical trial. The results from the study by Tempfer et al (1998) and Zeisler et al (1998) suggest benefits from giving pre-labour acupuncture treatment using relaxing acupuncture points as a preparation for labour.

As the results suggest that this intervention has little effect, it may be more effective to increase the frequency of treatment sessions, for example to give acupuncture every day from randomization to spontaneous labour/induction or perhaps every second day. It will be the project of future clinical trials to discover the optimal frequencies of pre-labour acupuncture treatments and the optimal interval between each treatment.

5.3.3 Control of other possible effects on the beginning of labour

The researcher considered asking the women to agree not to try sexual intercourse, nipple stimulation, castor oil or membrane sweeping to induce labour if they participated in this study. However, as the evidence is either too weak (sexual intercourse, nipple stimulation) or relatively strong (castor oil, membrane sweeping) it was not considered ethical to do so.

As membrane sweeping can promote the onset of labour at term, the researcher decided to document whether membranes were swept at the time of cervical assessment at 41 weeks and 41 weeks and 5 days (± 2 days). There was perhaps one woman in the control group who went spontaneously into labour due to membrane sweeping soon after randomization but her membranes had been swept earlier that same day.

It would have been appropriate to ask women after birth if they had tried castor oil in order to induce labour, in order to prevent a possible bias. It also would have been appropriate to have women agreeing to have no acupuncture treatment other than that offered in the study until labour began. These issues should be taken into consideration in a future clinical trial.

5.3.4 Practical issues

There seem to be no practical difficulties in following the intended method in a future clinical study. One relatively small improvement can be made to increase the quality of the study and ensure that it will truly be a single-blind randomized clinical trial. For a future clinical trial it is very important to ensure a quiet, comfortable and relaxing atmosphere in which the acupuncture treatment can take place. It is important to ensure that women have privacy and a calm environment in which to take part in the study and receive treatments, and to ensure blinding of midwives and physicians who are involved in the study.

5.4 Implications for practice

Complementary therapies are not necessarily safe even though they are natural and, according to Ernst et al (2003), perhaps the most dangerous side effect of any complementary treatment is a delay in receiving effective therapy. Acupuncture is considered to be safe when performed by an expert (Ernst et al, 2003). The evidence certainly suggest some benefits of the use of acupuncture for actuating spontaneous labour, induction of labour and augmentation of labour, but this needs to be assessed in well-designed clinical trials with adequate sample sizes. The evidence is stronger when it comes to pre-labour acupuncture for cervical ripening and preparation for labour as it seems to be effective in ripening the cervix and shortening the duration of labour. It is important not to delay effective treatments while offering safe complementary therapies with uncertain effectiveness, such as delaying medical induction while giving acupuncture treatment in the case of urgent

need for induction of labour. It is appropriate to offer women acupuncture as a preparation for labour in cases of non-urgent need for induction and for augmentation of labour, but it is important to provide accurate information about the effectiveness in order to give women the opportunity to make an informed choice.

6 Conclusion and Recommendations

6.1 Conclusion

This study serves as a pilot study for a future clinical trial, therefore, the sample size is too small to provide any statistically significant results. The tools of data collection seem to be reliable and only minor practical difficulties were encountered. Collection of more detailed demographic information and collection of data on more secondary outcome variables are suggested for a future clinical trial. Also suggested is a change regarding the facilities where acupuncture treatment takes place in a future study in order to increase convenience for the participants and the quality and reliability of the study. According to the study data, the intervention is probably of small effect size and therefore a large sample will be required for testing the effectiveness of this intervention in a future clinical trial.

6.2 Suggestion of further avenues for future research

Initially, the intention was to include both nulliparous and multiparous women but after careful consideration it was decided to include only nulliparous women. The rationale for this decision was that nulliparous women benefit more from spontaneous onset of labour than multiparous women as the Caesarean section rate is not increased when labour is induced in multiparous women whereas it probably is the case for nulliparous women. This rationale made me think about a group of women that are often excluded from all kinds of studies, i.e. women who have had a previous Caesarean section. It would be appropriate and safe to include these

women who are planning vaginal birth in a future clinical trial. They may benefit even more than nulliparous women of going into spontaneous labour or if their cervix ripens to become favourable enough to make amniotomy possible, as women who have had a previous Caesarean section are usually not induced with prostaglandins. Women with a previous Caesarean section were excluded from some studies (Rabl et al, 2001; Tempfer et al, 1998) but some studies do not mention whether they are included or excluded (Gaudernack et al, 2006; Kubista et al, 1975; Tsuei et al, 1977; Yip et al, 1976). No abnormal contractions or uterine hyper-stimulations have been reported in the literature reviewed here. There is no evidence to suggest that risk accompanies acupuncture for women with a previous Caesarean section in late pregnancy and, according to the literature, acupuncture could perhaps help these women to have a natural birth as there is concern that medical induction of labour can lead to uterine hyper-stimulation.

References

- Betts, D. (2006) *The essential guide to acupuncture in pregnancy & childbirth*. East Sussex, The Journal of Chinese Medicine Ltd. and Debra Betts.
- Bishop, E.H. (1964) Pelvic scoring for elective induction. *Obstetrics and Gynecology*, 24, 266–268.
- Boulvain M, Stan C, Irion O. Membrane sweeping for induction of labour. *Cochrane Database of Systematic Reviews* 1997, Issue 4. Art. No.: CD000451. DOI: 10.1002/14651858.CD000451.pub2. (Citation as instructed)
- Cardini, F. (2004) Acupuncture: Scientific evidence. *Ricerca e Pratica*, 20(5), 200–211.
- Carlsson, C. & Anckers, L. (1997) *Akupunktur och TENS inom obstetrike*. Lund, Studentlitteratur.
- Cluett, E. (2000) The onset of labour. 1: A review of the physiology. *The Practising Midwife*, 3(6), 16–19.
- Cohen, J.W. (1988) *Statistical power analysis for the behavioural sciences*, 2nd edn. Hillsdale, NJ: Lawrence Erlbaum Associates. Cited in Pallant, Julie (2007) *SPSS survival manual*, 3rd edn. New York: Open University Press.
- Cohen, J. (1992) A power primer. *Psychological Bulletin*, 112(1), 155–159.
- College of Midwives of British Columbia (2003) *Guidelines for post-dates pregnancy* [online]. College of Midwives of British Columbia. Available from:

http://www.cmbc.bc.ca/clinical_practice_guidelines/GuidelinesForPostDatesPregnancy.pdf [Accessed 4th of January 2006].

Cooke, P. (1997) Induction of labour and post-term pregnancy. *In*: B.R. Sweet & D. Tiran (eds) *Mayes' midwifery*, 12th edn. Edinburgh, Harcourt Publishers Limited. pp. 610–622.

Crowley P. Interventions for preventing or improving the outcome of delivery at or beyond term. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD000170. DOI: 10.1002/14651858.CD000170.pub2. (Citation as instructed)

Curtis, P., Coeytaux, R.R. & Hapke, P. (2006) Acupuncture for birth preparation and delivery: How investigating mechanisms of action can generate research. *Complementary Health Practice Review* [online], Available from: <http://www.sagepub.com/cgi/content/abstract/11/3/176>. [Accessed 2nd of May 2008].

Dörr, A. (1990) The possibility of inducing labor using acupuncture. *American Journal of Acupuncture*, 18(3), 213–218.

Ernst, G., Strzyz, H. & Hagmeister, H. (2003) Incidence of adverse effects during acupuncture therapy—a multicentre survey. *Complementary Therapies in Medicine*, 11(2), 93–97.

Ewies, A.A. & Olah, K.S. (2002) The sharp end of medical practice: the use of acupuncture in obstetrics and gynaecology. *BJOG*, 109(1), 1–4.

- Garry, D., Figueroa, R., Guillaume, J. & Cucco, V. (2000) Use of castor oil in pregnancies at term. *Alternative Therapies*, 6(1), 77–79.
- Gaudernack, L.C., Forbord, S. & Hole, E. (2006) Acupuncture administered after spontaneous rupture of membranes at term significantly reduces the length of birth and use of oxytocin. A randomized controlled trial. *Acta Obstetrica et Gynecologica Scandinavica*, 85(11), 1348–1353.
- Gilbert, E.S. & Harmon, J.S. (1998) *Manual of high risk pregnancy & delivery*, 2nd edn. St Louis, Mosby.
- Glantz, J.C. (2005) Elective induction vs. spontaneous labor associations and outcomes. *The Journal of Reproductive Medicine*, 50(4), 235–240.
- Gülmezoglu AM, Crowther CA, Middleton, P. Induction of labour for improving birth outcomes for women at or beyond term. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD004945. DOI: 10.1002/14651858.CD004945.pub2. (Citation as instructed)
- Harper, T.C., Coeytaux, R.R., Chen, W., Campbell, K., Kaufman, J.S., Moise, K.J. & Thorp, J.M. (2006) A randomized controlled trial of acupuncture for initiation of labor in nulliparous women. *The Journal of Maternal-Fetal and Neonatal medicine*, 19(8), 465-470.
- Kavanagh J, Kelly AJ, Thomas J. Sexual intercourse for cervical ripening and induction of labour. *Cochrane Database of Systematic Reviews* 2001, Issue 2.

Art. No.: CD003093. DOI: 10.1002/14651858.CD003093. (Citation as instructed)

Kubiena, G. (1989) Considerations on the concept of placebo in acupuncture. Reflections on the usefulness, ethical justification, standardization and differentiated application of placebo in acupuncture. *Wiener Klinische Wochenschrift*, 101(10), 362–367.

Kubista, E. & Kucera, H. (1974a) Acupuncture as a method of preparation in obstetrics. *American Journal of Chinese Medicine*, 2(3), 283–287.

Kubista, E. & Kucera, H. (1974b) Über die Anwendung der Akupunktur zur Geburtstsvorbereitung. *Zeitschrift für Geburtshilfe und Perinatol*, 178, 224–229.
Cited in Sven Lyrenäs, Helen Lutsch, Jerker Hetta & Bo Lindberg (1987) Acupuncture before delivery: Effect on labor. *Gynecologic and Obstetric Investigation*, 24, 217–224.

Kubista, E., Kucera, H. & Muller-Tyl, E. (1975) Initiating contractions of the gravid uterus through electro-acupuncture. *The American Journal of Chinese Medicine*, 3(4), 343–346.

Landspítali University Hospital (2007) *Skýrsla frá faedingarskráningunni fyrir árið 2006*. Reykjavík, Kvennadeild og Barnspítali Hringisins Landspítali University Hospital.

Ledergerber, C.P. (1976) Electroacupuncture in obstetrics. *Acupuncture and Electro-Therapeutic Research. The International Journal*, 2, 105–118.

- Lockwood, C.J. (2004) The initiation of parturition at term. *Obstetrics and Gynecology Clinics of North America*, 31, 935–947.
- Lyrenäs, S., Lutsch, H., Hetta, J. & Lindberg, B. (1987) Acupuncture before delivery: Effect on labor. *Gynecologic and Obstetric Investigation*, 24, 217–224.
- MacPherson, H., White, A., Cummings, M., Jobst, K., Rose, K. & Niemtzw, R. (2001) Standards for reporting interventions in controlled trials of acupuncture: the STRICTA recommendations. *Complementary Therapies in Medicine*, 9(4), 246–249.
- Manheimer, E., Zhang, G., Udoff, L., Haramati, A., Langenberg, P., Bergman, B.M. & Bouter, L.M. (2008) Effects of acupuncture on rates of pregnancy and live birth among women undergoing in vitro fertilisation: systematic review and meta-analysis. *British Medical Journal*, 336, 545–549.
- Maslow, A.S. & Sweeny, A.L. (2000) Elective induction of labor as a risk factor for cesarean delivery among low-risk women at term. *Obstetrics and Gynecology*, 95(6), 917–922.
- Medforth, Janet et al. (eds) (2006) *Oxford handbook of midwifery*. Oxford; New York, Oxford University Press.
- Mendelson, C.R. & Condon, J.C. (2005) New insights into the molecular endocrinology of parturition. *The Journal of Steroid Biochemistry and Molecular Biology*, 93(2–5), 113–119.

- Morgan, M.A., Goldenberg, R.L. & Schulkin, J. (2007) Obstetrician-gynecologists' knowledge of preterm birth frequency and risk factors. *Journal of Maternal-Fetal and Neonatal Medicine*, 20(12), 895–901.
- Morrin, N.A. (1997) Midwifery care in the first stage of labour. *In*: B.R. Sweet & D. Tiran (eds) *Mayes' Midwifery. A textbook for midwives* 12th edn. London, Baillière Tindall. pp. 355–384.
- Pallant, J. (2007) *SPSS survival manual*, 3rd edn. New York: Open University Press.
- Pei-chong, L. (1998) Acupuncture to accelerate labour. *International Journal of Clinical Acupuncture*, 9(4), 459–462.
- Polit, D.F. & Beck, C.T. (2006) *Essentials of nursing research: methods, appraisal, and utilization*, 6th edn. Philadelphia, Lippincott Williams & Wilkins.
- Pollnow, D.M. & Broekhuizen, F.F. (1996) Randomized, double-blind trial of prostaglandin E2 intravaginal gel versus low-dose oxytocin for cervical ripening before induction of labor. *American Journal of Obstetrics and Gynecology*, 174(6), 1910–1916.
- Proud, J. (1997) *Understanding obstetric ultrasound: its use and interpretation*, 2nd edn. Hale, Cheshire, Books for Midwives Press.
- Rabl, M., Ahner, R., Bitschnau, M., Zeisler, H. & Husslein, P. (2001) Acupuncture for cervical ripening and induction of labor at term – a randomized controlled trial. *Wiener Klinische Wochenschrift*, 113(23–24), 942–946.

- Royal College of Obstetricians and Gynaecologists (2001) *Induction of labour. Evidence-based clinical guideline number 9*. London, RCOG Press.
- Rees, C. (2003) *An introduction to research for midwives*, 2nd edn. Edinburgh; New York, Elsevier Science.
- Romer, A., Weigel, M., Zieger, W. & Melchart, F. (2000) Prenatal acupuncture: effects on cervical maturation and duration of labour. *Geburtshilfe und Frauenheilkunde*, 60(10), 513–518.
- Runarsdottir, H.B. (2004) *Nalastungur i faedingu*, Candida Obstetricum edn. University of Iceland, Department of Nursing, Midwifery School, Reykjavik.
- Sanchez-Ramos, L., Olivier, F., Delke, I. & Kaunitz, A.M. (2003) Labor induction versus expectant management for post-term pregnancies: a systematic review with meta-analysis. *Obstetrics and Gynecology*, 101(6), 1312–1318.
- Secker-Walker, R.H. & Vacekb, P.M. (2003) Relationships between cigarette smoking during pregnancy, gestational age, maternal weight gain, and infant birthweight. *Addictive Behaviors*, 28(1), 55–66.
- Selmer-Olsen, T., Lydersen, S. & Morkved, S. (2007) Does acupuncture used in nulliparous women reduce time from prelabour rupture of membranes at term to active phase of labour? A randomised controlled trial. *Acta Obstetricia et Gynecologica Scandinavica*, 86(12), 1447–1452.
- Siozos, C. & Stanley, K.P. (2005) Prolonged Pregnancy. *Current Obstetrics and Gynaecology*, 15, 73–79.

- Skilnand, E., Fossen, D. & Heiber, E. (2002) Acupuncture in the management of pain in labour. *Acta Obstetrica et Gynecologica Scandinavica*, 81(10), 943–948.
- Smith, C., Crowther, C. & Beilby, J. (2002) Pregnancy outcome following women's participation in a randomised controlled trial of acupuncture to treat nausea and vomiting in early pregnancy. *Complementary Therapies in Medicine*, 10(2), 78–83.
- Smith CA, Crowther CA. Acupuncture for induction of labour. Cochrane Database of Systematic Reviews 2004, Issue 1. Art. No.: CD002962. DOI: 10.1002/14651858.CD002962.pub2. (Citation as instructed)
- Summers, L. (1997) Methods of cervical ripening and labor induction. *Journal of Nurse-Midwifery*, 42(2), 71–85.
- Tempfer, C., Zeisler, H., Heinzl, H., Hefler, L., Husslein, P. & Kainz, C. (1998) Influence of acupuncture on maternal serum levels of interleukin-8, prostaglandin F2alpha, and beta-endorphin: a matched pair study. *Obstetrics and Gynecology*, 92(2), 245–248.
- Tenore, J.L. (2003) Methods for cervical ripening and induction of labor. *American Family Physician*, 67(10), 2123–2128.
- Tiran, D. (2006) Late for a very important date. *The Practising Midwife*, 9(3), 16–21.
- Tremeau, M.L., Fontanie-Ravier, P., Teurnier, F. & Demouzon, J. (1992) The protocol for cervical maturation using acupuncture. *Journal de Gynecologie Obstetrique et Biologie de la Reproduction*, 21(4), 375–380.

- Tsuei, J.J., Lai, Y. & Sharma, S.D. (1977) The influence of acupuncture stimulation during pregnancy: the induction and inhibition of labor. *Obstetrics and Gynecology*, 50(4), 479–488.
- Tsuei, J.J. & Lai, Y.F. (1974) Induction of labor by acupuncture and electrical stimulation. *Obstetrics and Gynecology*, 43(3), 337–342.
- Vahratian, A., Zhang, J., Troendle, J.F., Sciscione, A.C. & Hoffman, M.K. (2005) Labor progression and risk of cesarean delivery in electively induced nulliparas. *Obstetrics and gynecology*, 105(4), 698–704.
- Vrouenraets, F.P., Roumen, F.J., Dehing, C.J., van den Akker, E.S., Aarts, M.J. & Scheve, E.J. (2005) Bishop score and risk of cesarean delivery after induction of labor in nulliparous women. *Obstetrics and Gynecology*, 105(4), 690–697.
- Wadhwa, P.D., Garite, T.J., Porto, M., Glynn, L., Chicz-DeMet, A., Dunkel-Schetter, C. & Sandman, C.A. (2004) Placental corticotropin-releasing hormone (CRH), spontaneous preterm birth, and fetal growth restriction: A prospective investigation. *American Journal of Obstetrics and Gynecology*, 191(4), 1063–1069.
- Weiss, J.L., Malone, F.D., Emig, D., Ball, R.H., Nyberg, D.A., Comstock, C.H., Saade, G., Eddleman, K., Carter, S.M., Craigo, S.D., Carr, S.R. & D’Alton, M.E. (2004) Obesity, obstetric complications and Caesarean delivery rate—a population-based screening study. *American Journal of Obstetrics and Gynecology* 190, 1091–1097.

West, Z. (2001) *Acupuncture in pregnancy and childbirth*. Edinburgh; New York, Churchill Livingstone.

WHO (2002) *Acupuncture: Review and analysis of reports on controlled clinical trials [online]*. WHO. Available from: <http://whqlibdoc.who.int/publications/2002/9241545437.pdf> [Accessed 3rd of January 2006].

Wikipedia, the free encyclopedia (2007) *Cun [online]*. *Wikipedia, the free encyclopedia*. Available from: <http://en.wikipedia.org/wiki/Cun> [Accessed 21st of April 2008].

Yelland, S. (2005) *Acupuncture in midwifery*, 2nd edn. Edinburgh; New York, Elsevier.

Yip, S.K., Pang, J.C. & Sung, M.L. (1976) Induction of labor by acupuncture electro-stimulation. *The American Journal of Chinese Medicine*, 4(3), 257–265.

Zeisler, H., Tempfer, C., Mayerhofer, K., Barrada, M. & Husslein, P. (1998) Influence of acupuncture on duration of labor. *Gynecologic and Obstetric Investigation*, 46(1), 22–25.

Zeisler, H., Rabl, M., Joura, E.A., & Husslein, P. (2000). Prenatal acupuncture and serum prostaglandin E2 levels during the first stage of labor. *Geburts Frauenheilk* , 60, 638-640.

Appendix 1: Forms for data collection

The forms used in the study were written in Icelandic and have been translated into English.

- **Demographical and maternal information**
- **41 weeks (\pm 2 days)**
- **41 weeks and 5 days (\pm 2 days)**
- **Cervical ripening – modified Bishop score**
- **Assessment of outcome**

Appendix 2: Letters used in the study

These letters are in Icelandic as they were written for Icelandic midwives and Icelandic women. They have not been translated.

- **Introductory letter for midwives in the primary health care [Kynningarbréf fyrir ljósmæður í mæðravernd]**
- **Introductory letter for prospective participants [Kynningarbréf]**
- **Letter of informed consent [Samþykki fyrir þátttöku í rannsókn]**

Appendix 3: Copies of letters and applications

The letters to and from the National Bioethics Committee are the only letters written in English. Other letters are written in Icelandic and have not been translated.

- **A letter dated 9 November 2007 to Landspítali University Hospital. *Subject: Request on whether the study can be conducted at the hospital.***
- **A letter dated 3 January 2008 from Landspítali University Hospital. *Subject: Permission to conduct a pilot study at the hospital granted.***
- **A letter dated 9 November 2007 to the Primary Health Care of the Capital Area in Iceland. *Subject: Request on a cooperation conducting a pilot study.***
- **A letter dated 29 January 2008 from the Primary Health Care of the Capital Area in Iceland. *Subject: Agree to cooperate with a pilot study.***
- **Application to the Data Protection Authorities in Iceland. Dated 8 November 2008.**
- **Permission from the Data Protection Authorities in Iceland. Dated 19 December 2008.**
- **Letter from the Data Protection Authorities in Iceland where they confirm that they received announcement from the researcher about process of personal data. Dated 25 March 2008.**

- **E-mail from Richard J. Hudson, Secretary of the University Research Ethics Committee confirming the robustness of the National Bioethics Committee in Iceland.**
- **Application to the National Bioethics Committee in Iceland. Dated 4 January 2008.**
- **Letter from the National Bioethics Committee in Iceland. Dated 22 January 2008. Subject: Concerns about giving no treatment to the control group.**
- **Letter to the National Bioethics Committee in Iceland. Subject: A reply to letter dated 22 January. Dated 7 February 2008.**
- **Letter from the National Bioethics Committee in Iceland. Dated 19 February 2008. Subject: Full approval for a pilot study.**

Appendix 4: List of tables and figures

List of tables

Table 2.1: Summary of studies about acupuncture and induction of labour	27
Table 3.1: Modified Bishop score	54
Table 4.1: Demographic and maternal information at the time of randomization	58
Table 4.2: Time from randomization to the onset of the active stage of labour	60
Table 4.3: Cervical ripening from randomization to second assessment at 41 weeks and 5 days	60
Table 4.4: Mean of Bishop score at randomization and at 41 weeks and 5 days (+/- 2 days).....	61
Table 4.5: Frequencies for spontaneous labour and inductions of labour	63
Table 4.6: Duration of labour	63
Table 4.7: Mode of birth	65
Table 4.8: Use of pain relieving agents.....	66
Table 4.9: Use of amniotomies and Oxytocin to augment spontaneous labour	67
Table 4.10: Use of amniotomies and pharmacological agents to induce labour and augment induced labour	68
Table 4.11: Postpartum blood loss	68
Table 4.12: Apgar scores.....	69

List of figures

Figure 3.1: Sanyinjiao (SP6).....	51
Figure 3.2: Hegu (LI4)	52
Figure 4.1: Flowchart of study participants	59
Figure 4.2 Mode of birth	64
Figure 4.3 Use of pain relief during labour	66

Appendix 5: Tables of raw data

- **Excel tables including all the raw data from the study.**