

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should speak to us – our contact details can be found at the end of this document. If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism is available to you

Data Protection

The study staff will ensure that the participants' anonymity is maintained by allocating a participants' unique code which will be used throughout the study. All documents will be stored securely throughout the study in the Chief Investigators and R&D Department Offices and will be accessible for a minimum of 15 years on completion of the study.

Who is organising and funding the research?

The research is being led by Sarah Gregson, Consultant Midwife, with support from the Research and Development Department. We anticipate that the study will last for approximately 6 months.

Who has reviewed the study?

The study has been reviewed and approved by London – Camden and Kings Cross Research Ethics Committee

What if I have a complaint or have further questions or concerns??

Please contact Mrs Sarah Gregson, Consultant Midwife
Tunbridge wells Hospital, Tunbridge Wells TN24 4QJ

☎ Via Maternity liaison office 01892 633488

Patient Advice and Liaison Service (PALS)

If you would like to comment on Trust services, have concerns or need information, you can contact the Patient Advice and Liaison Service (PALS) ☎ 01892 632953

Research Study:

Acupuncture for treatment of slow labour

Information leaflet for women



A study to investigate if acupuncture can help treat slow labour

You are being invited to take part in a research study. Before you decide whether to take part it is important that you understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with your midwife, doctor or family and friends if you wish. Please ask us if you would like more information or if anything is not clear.

What is Acupuncture and what are we trying to find out?

Acupuncture is treatment that involves inserting fine needles into the body. It is believed to have originated in China, but has been increasingly accepted within Western medicine during the last 30 years. It is widely used by midwives in other European countries including Germany and Sweden for pain relief in labour.

Research has already shown that acupuncture can:

- Reduce labour pain intensity
- Shorten labour
- Reduce need for forceps or ventouse to deliver the baby

The purpose of this study is to find out if acupuncture can be used to treat an established labour that has slowed down, instead of using a drip with a hormone drug to speed up contractions.

Why have I been chosen and do I have to take part in the study?

You will be able to take part in the study if your midwife or doctor diagnoses that your labour is slower than normal and your waters around the baby have not broken naturally. A 'slow labour' is usually diagnosed if the cervix (neck of the womb) dilates less than 2cm in 4 hours, after it has become established.

You do not have to take part, but if you agree, you will be asked to sign a consent form. Your participation is voluntary and you are free to withdraw at any time, without giving any reason and without medical care or legal rights being affected.

What usually happens if labour slows down?

The usual treatment for a labour that has slowed down is to break the waters around the baby, (if this has not already happened naturally). This can sometimes help labour to progress, but if not a hormone drip is commenced 2 hours later. This can make the contractions more painful and it also means that you will have to have the baby's heartbeat monitored continuously to make sure that it remains normal.

What will happen to me if I take part in the study?

The research method that we intend to use is a randomised controlled trial which means we will study two groups of women, who have their waters broken for a 'slow labour'. One group will have acupuncture, the other will have 'normal care' (wait for 2 hours). The two groups are

selected by a computer, which means they are selected by chance. All women will receive one-to-one care throughout labour.

If you are selected to be in the acupuncture group

Acupuncture needles will be inserted to points on your legs and hands. The needles are so fine that most women barely feel anything at all, however sometimes a slight sharp sensation is felt as the needle passes through the skin. The needles will remain in place for 30 to 40 minutes, and then will usually be removed. After this, you may choose to have further treatments for the rest of your labour, if you feel it is helping you to cope better.

If you are selected to be in the 'control' group

You will receive 'normal care'. This means waiting for 2 hours after your waters have broken, to see if progress in labour improves.

For both groups

After 2 hours you will have another vaginal examination. If you have made adequate progress (the cervix has dilated 2cm or more), then no further treatment will be given. If you have not made adequate progress, then a hormone drip will be commenced. This will also mean that the baby's heartbeat will be monitored continuously until your baby is born.

After the birth of your baby, you will be asked to complete a short questionnaire about your experience before you go home.

Are there any risks involved?

There are no major risks associated with the acupuncture treatment that will be used in this study, however sometimes it can make some women feel a little drowsy because it helps stimulate endorphins (which are the body's natural pain killers). Occasionally there can be minor bleeding from the point of the needle. This can be easily treated by pressing firmly on the area for a few minutes.

What are the benefits of taking part in this study?

We hope the information we get from this study will help us to know whether acupuncture should be offered routinely when labour is delayed.