Participant Information Leaflet

Northern & Yorkshire Research Ethics Committee Reference: 09/H0903/31
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ISRCTN98680152

Title of project: A study of an intelligent system to support decision making in the management of labour using the cardiotocograph – the INFANT study.

Chief Investigator: Professor Peter Brocklehurst

Invitation to join the INFANT study

You are being invited to take part in a research study called the INFANT study. The study is finding out if we can further improve the way we monitor baby's well-being during labour.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. If you decide not to take part this will not affect the standard of care you will receive.

The rest of this leaflet explains the study in more detail and describes what being in the study would mean for you.

Title of project: A study of an intelligent system to support decision making in the management of labour using the cardiotocograph – the INFANT study.

What is the purpose of the study?

Midwives or doctors caring for women in labour often use electronic fetal monitoring – more specifically this is called a cardiotocograph or CTG. This gives information about the baby's heart rate and also on the activity of the uterus (contractions). Doctors and midwives currently have to interpret these by eye alone. Looking at a recording of the baby's heart rate and interpreting it is complicated and we are constantly looking for ways to make this more accurate. We therefore want to see if a computer system, that is a system that can analyse information electronically, can help the doctors and midwives looking at this information, and whether this will be more beneficial to you and your baby (or babies if you are having twins).

Why am I being asked to consider the study?

You are being asked to consider taking part in this study as at some point during your antenatal care or labour, a decision may be made to recommend that your baby's heart rate is monitored continuously during labour. This is a common procedure which many tens of thousands of women have each year. We know that many women do not require continuous monitoring of their baby's heart rate. However, sometimes this may become necessary during labour, so we want to let all women know about the study so they can think about whether they would like to take part or not. Agreeing to take part in the study will not determine whether or not you receive monitoring - this decision is made by you and your health professionals.

We hope that 46,000 women across the UK and Ireland will agree to participate in this study, of whom 23,000 will receive standard care and 23,000 will have standard care as well as use the 'intelligent' computer system.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information leaflet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

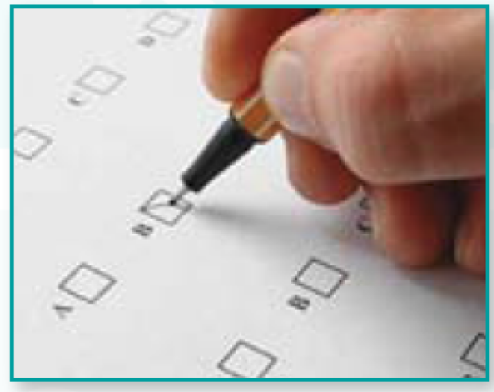
What would happen to me if I take part?

If you are happy to take part in the study, you will be asked to sign a consent form. If then continuous electronic fetal monitoring is started, your electronic monitoring would then be either (i) standard care, with your health care team looking at your readings from the monitor, or (ii) your monitoring will be looked at by the 'intelligent'

computer system as well as your health care team. The decision about which group you would be in would be made by chance, rather like the toss of a coin. This is important because it ensures that the 'intelligent' computer will be tested fairly.

What would being in the study involve?

Information will be collected during your labour on a monitoring machine. This information will be kept strictly confidential. We will also record details of when you and your baby are discharged from the hospital, and details of any treatments you and your baby receive whilst in hospital. For the majority of women this is all the information and contact that you would have with the INFANT study – and we would be pleased to include you and your baby. We would also like to register your baby's inclusion in the INFANT study with the NHS Information Centre (IC) to provide ongoing information on your baby's health status to the study team until the end of the study – this would not involve any direct contact from the study or the NHS IC.



However, we would also like to find out a bit more about 7,000 of the 46,000 babies that enter the INFANT study. This would involve asking for an extra consent and signature from you that would allow the study team to contact you with some questionnaires at 1 and 2 years after the birth of your baby. These questionnaires would ask how your baby is and about their and your general health and in some cases there would be a questionnaire asking about how often you have used the NHS since giving birth. The women and babies followed up would be chosen by chance from those that agree to the further follow-up.

There are no further tests or hospital visits or any payments available for taking part in this study.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help improve the care provided to women in labour in the future.

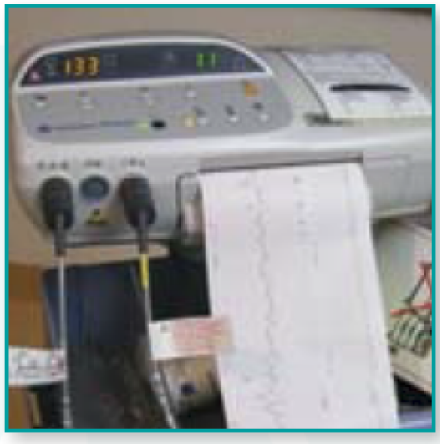
Will my taking part in the study be kept confidential?

Yes. All information we collect about you will be handled in confidence. This completes the introduction to the study. If, after reading this, the study sounds like something you may be interested in and you are considering taking part, please read the following additional information before making any decision.

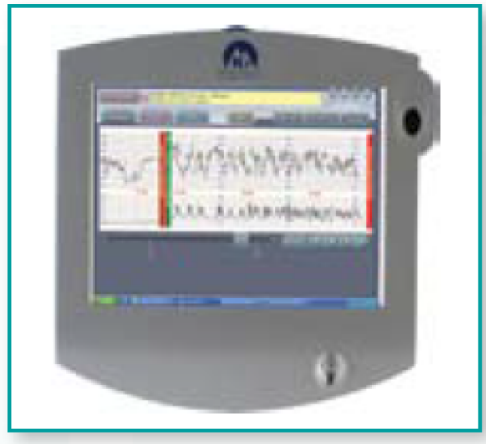
Additional Information about the INFANT study

More about continuous monitoring

Most babies have no problems coping with labour, but there are a few who don't cope so well. During contractions blood can't get through the placenta so easily. This is normal and most babies cope without any problems. If a baby is not coping well, this may be reflected in the pattern of their heart rate. About 60% of women in the UK have continuous monitoring of their baby's heart rate during labour, with a machine called a cardiotocograph or CTG . This machine allows doctors and midwives to monitor your baby's heart rate and your contractions and record them.

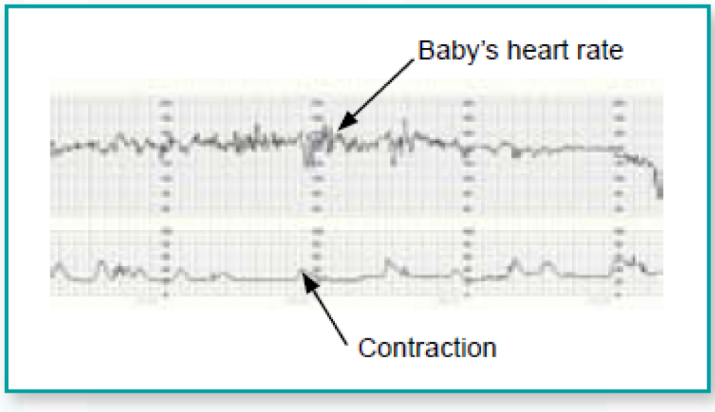


A CTG machine

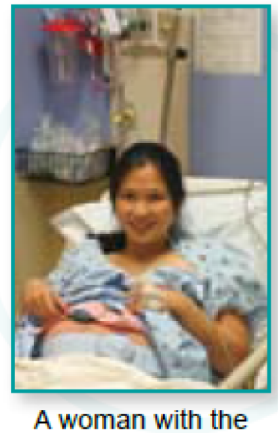


The computer that displays the traces

This recording is obtained by placing two plastic pads onto your abdomen: one records the heart rate; one records the contractions, and it sends the outputs from them to a computer that is next to the bed in every labour room.



An example of a trace from the CTG

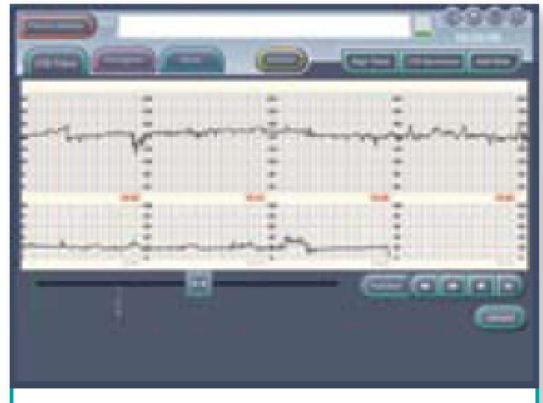


A woman with the CTG pads attached

Continuous monitoring keeps track of your baby's heart rate for the whole of your labour and allows doctors and midwives to check on the health of your baby.

Being attached to the monitor can limit your ability to move around. You should still be able to stand or sit up, although it may not be possible to have a bath or walk around. Ask your midwife to help you get as comfortable as possible. In some cases, you may be asked for permission to apply a small clip called a Fetal Scalp Electrode (FSE) to the skin on the baby's head. This is then connected to the CTG machine to obtain a more accurate recording.

Currently in the UK, doctors and midwives regularly look at the traces produced by the CTG machine to decide how best to look after you and your baby. In this study, half of the women that agree to take part and go onto receive continuous electronic fetal monitoring, would also have a computer system also looking at the traces. The computer system will tell the doctors and midwives if there are any changes to the baby's heart rate that the doctors and midwives need to be aware of. The computer system will do this by changing the colour of the bar at the top of the computer screen that is showing the CTG. At times the monitor may also give out a sound when the computer screen has changed colour.



An example of what the screen looks like if your labour is looked at by the computer system as well as the doctors and midwives

However, for all women, the final decisions made about you and your baby's care is by the doctors and midwives, the 'intelligent' computer is just giving them more information.

You mention sending a questionnaire later. What will the questionnaire contain?

The questionnaire is in two parts. One section will ask about how your child is, and the second section about how you are. A small number of the families that agree to be followed up will also be invited to complete an additional questionnaire about how often they have visited their GP and hospital over the 2 years after giving birth. The questionnaire will be posted out from the co-ordinating office at University College London. Once completed, it can be returned in a freepost envelope (no stamp required), which is supplied. The first questionnaire will be sent twelve months after giving birth, and the second one will be sent twelve months after the first.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. In order to be able to contact you about your own and your baby's health in the future, your name and contact details will be made available to the researchers running this study and held at the co-ordinating centre in London, and not just your local study doctor. These details will be kept securely, with access restricted. You will not be named or otherwise identified in any study publication.

Who is organising and funding the research?

Researchers at the Clinical Trials Unit (CTU) at University College London are organising this research and work with the doctors and midwives in hospitals around the UK and Ireland.

The National Coordinating Centre for Health Technology Assessment (part of the Department of Health/UK Government) is funding the research.

Who has approved the study?

This study has been reviewed and given a favourable opinion by a NHS Research and Ethics Committee (REC). The REC looks after the rights, well being and dignity of patients. The REC reference number is given on the front page of this document. This study was also reviewed by the National Coordinating Centre for Health Technology Assessment before it was awarded funding to ensure it met the necessary scientific standards.

Is there a contact point where I can seek independent advice about participating in the study?

If you would like more information about the study itself you can ask to speak to the lead doctor or midwife for the INFANT study at this hospital. These details are on the back page of this leaflet.

The hospital's PALS Office (Patient Advice and Liaison Service) can also be contacted. They will give you advice about how to contact someone for independent advice. Ask one of the doctors or midwives for their office details.

Are there any risks?

This study is evaluating if the addition of a computer system is of help to doctors and midwives. You will still receive the same level of monitoring from the doctors and midwife whether you participate in the study or not.

What if there is a problem?

If you have a concern about any aspect of this study, you should first speak to the lead INFANT study Doctor or the INFANT study Research Midwife. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Compensation for harm arising from an accidental injury and occurring as a consequence of your participation in the study will be covered by University College London. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against University College London (in respect of any harm arising out of participation in the study) or the NHS (in respect of any harm which has resulted from the clinical procedure being undertaken).

Where can I find the results of the study?

The results of the study will be published in a medical journal and on the study website when the study has finished (www.ucl.ac.uk/ctu/infant). We will send out a summary of the study findings to all participants when the study is published. You will not be identified in any report or publication.

Thank you for taking time to read this information.

Local contacts

{_LEAD_} **{_MIDWIVES_}**

INFANT Study Co-ordinating Team

[redacted]

[redacted]

This study is being organised by the Clinical Trials Unit at University College London. One of the aims of the Unit is to improve the care provided to women and their families during pregnancy, childbirth and the period after birth, as well as the care provided to the newborn.
www.ucl.ac.uk/ctu/infant

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