Thank you for taking the time to read this.

For further information please ask to speak to:

Nottingham
Dr Jon Dorling
Consultant Neonatologist
Tel: 0115 9249924 ext. 62429

Dr Bernard Schoonakker
Consultant Neonatologist
Tel: 0115 9691169 ext. 55142

Improving quality of care and outcome at very preterm birth
NIHR Programme Grant for Applied Research

Nottingham University Hospitals NHS
NHS Trust

Parent Information

Measuring placental transfusion in babies born early (prematurely)

Bliss
for babies born too soon, too small, too sick

Improving quality of care and outcome at very preterm birth
NIHR Programme Grant for Applied Research

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Thank you for taking the time to read this information sheet and to consider this study.

Please see the contact details on the reverse of this leaflet.

17/12/11 [Final version 2]

What about the results?

These will be presented at hospitals, conferences and published in academic journals. Unless you ask us not to, we will send you a lay summary of the study results, and updates on the programme.

Who is organising this research?

The research is part of a programme of research run by Professor Lelia Duley at the Nottingham University Hospitals NHS Trust, funded by the National Institute of Health Research. It is taking place at three hospitals, two in Nottingham and one in Bradford. Nottingham University Hospitals NHS Trust is sponsoring this study.

Who has reviewed the study?

This study was given favourable ethical opinion for conduct in the NHS by London - Riverside Research Ethics Committee and has been reviewed and approved by the Research and Innovation Department on behalf of the Sponsor, Nottingham University Hospitals NHS Trust.

Contact for further information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedure involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

If you decide you would like to take part then you will be asked to read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

An invitation to take part in this research study…

You are being invited to take part in a research study about the timing of clamping the umbilical cord at birth in babies born early.

What is this research about?

For many years the umbilical cord was clamped immediately at birth. However, not clamping the cord immediately allows the blood flow to continue in the cord for a short while. The blood which transfers to the baby during this time is known as 'placental transfusion' and it gives the baby more blood at birth.

The national recommendations are now to wait for at least 30 seconds before clamping the cord as this reduces the chance of babies needing a blood transfusion. However, in premature babies, we do not really know how long is best to wait nor how much blood transfers to the baby if the cord is left unclamped. Nor do we know for certain the potential benefits or possible harms of leaving the cord unclamped or of clamping the cord early. This study is to measure the amount and length of placental transfusion in babies born too early.

Can I/we take part?

You are eligible to take part if you give birth before the 36th week of pregnancy.

Do I/we have to agree to take part?

No. Whether or not you choose to participate is entirely up to you. Your care and your baby's care will not be affected in any way if you decide not to participate.

Can I change my mind?

Yes. If you do take part, you are free to withdraw at any time without giving a reason and your baby's care will not be affected in any way.

What does this study involve?

The study involves your baby being placed on digital weighing scales next to your bed for up to 5 minutes at birth. During this time your baby will be wrapped in towels and or a plastic wrapping/bag to keep warm, but the umibilical cord will not be clamped and you will not be able to touch your baby until the weighing is finished. During the weighing your baby's heart rate and temperature will be monitored. Once the weighing is finished, the cord will be clamped and cut, and care will continue as normal. We would also like to take some details about the birth and your baby from hospital records.

What are the possible risks of taking part?

We need to be careful that your baby is kept warm enough during weighing. In keeping with normal practice, to keep your baby at the right temperature we will warm the birthing room, wrap your baby in warm towels and plastic wrapping, and use warming mattresses or overhead heaters as needed. Another issue is that premature babies sometimes need support for their breathing or help with their heart beat. To ensure such help isn't delayed by waiting for the cord to be clamped, an experienced doctor (a neonatologist) will be present at the birth. This Doctor can ask for the cord to be clamped and the weighing stopped at any time, if necessary. Other possible harmful effects include too many blood cells in babies and higher levels of jaundice. We will carefully look for these and treat them if needed. We will carefully record and act to prevent the recurrence of any problems that are seen in the study.

What are the possible benefits?

There are many possible benefits including improved blood cell levels, iron stores, oxygen supply to the brain and a reduction in the number and extent of bleeding in the brain. Together these may improve the long term brain function of these infants. We do not know the best time to clamp the umbilical cord, and so we are not sure whether taking part in this study will benefit you or your baby. The results of this study will help us design research to test whether different approaches to cord clamping improve the health of babies born too early.

What are the alternative treatments

The other options are to clamp the cord soon after your baby is born or to defer cord clamping for a period of time. The midwife or obstetrician assisting your delivery will be able to advise on this.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. 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. In the event that something does go wrong and you or your baby are harmed during the research study there are no special compensation arrangements. If you or your babies are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my part in this study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital and at Nottingham University Hospitals NHS Trust under the provisions of the 1998 Data Protection Act. You or your babies names will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.