

Parent Information

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
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**Measuring placental transfusion in babies
born at term**



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



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Figure 1: Set up of scales next to delivery room bed



Figure 2: Set up of scales on resuscitaire next to delivery room bed, doll demonstrating closeness to mother during weighing.



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.

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

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.

What is this research about?

For many years the umbilical cord was clamped immediately at birth. However, when the cord is not clamped immediately, blood continues to flow through 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.

In the UK, current guidance is to wait for at least 30 seconds before clamping the cord, if that is possible. However, we do not really know how long is best to wait. For premature births we know very little about placental transfusion. To help us understand more about placental transfusion in premature births, our study aims to measure the volume and duration of placental transfusion by weighing babies at birth before the cord is cut. Before we do this at premature births we need to train our team, and it is best to do this with term births because this has already been done by another team of midwives in our research group.

Can I/we take part?

You are eligible to take part in this training phase if you give birth after the 37th week of pregnancy.

Do I/we have to agree to take part?

No. Whether or not you 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.

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 we will keep your baby warm, and the umbilical cord will not be clamped. We ask that you do not touch the baby until weighing is complete because the scales are very sensitive. During the weighing your baby's heart rate and temperature will be monitored. Once weighing is finished, we will encourage skin-to-skin contact with your baby if you wish and care will continue as normal.

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 use warming mattresses or overhead heaters as needed. An experienced doctor (a neonatologist) will be present at the birth and monitor your baby. 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?

Possible benefits include improved blood cell levels, and iron stores. 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 baby 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. Neither your nor your baby's name will be passed to anyone apart from the research team and the study sponsor and your details will not be shared with any outside parties. You will be allocated a study number, which will be used as a code to identify you on all study 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.

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.