NATIONAL WOMEN'S HOSPITAL

AUCKLAND DISTRICT HEALTH BOARD
Te Toka Tumai

Phone: (09) 307 4949
Fax: 09-375-4344
Address: Level 9 Support Building
Auckland City Hospital
Postal Address: Private Bag 92-024
Auckland

PARTICIPANT INFORMATION AND CONSENT FORM

You are invited to join a research study. Please feel free to ask questions. You may wish to discuss this study with relatives or friends.

Study Title: Should very preterm babies receive a placental transfusion at birth? A randomised controlled trial.

Short Title: Australian Placental Transfusion Study (APTS)

Principal Investigator: Katie Groom

1. What is the purpose of this study?

This study will compare two ways of caring for babies at birth. The first is standard practice - clamping the umbilical cord at birth immediately so that care of the baby and delivery of the placenta (the third stage of labour) can start straight away. The second is to let the baby get extra blood by holding the baby below the level of the placenta and waiting for a minute or more before clamping the cord. This is called placental transfusion.

Placental transfusion may help preterm babies by preventing anaemia and improving low blood flow. This may reduce bleeding in the brain, lung and gut problems, infections and need for blood transfusions.

2. Why have I been asked to participate in this study?

Your baby may be born before 30 weeks gestation – more than 10 weeks early. This means that you can join the study. The study will recruit up to 1600 babies.

3. What if I don't want to take part in this study, or if I want to withdraw later?

You don't have to take part and you can withdraw without a reason. This wouldn't affect your care. Please ask the study team any questions you wish. Only sign the consent form if you are happy with the answers. We'll let you know if information comes out that may affect your choice about the study.

4. What does this study involve?

If you consent and you go into labour or have a Caesarean section before 30 weeks, the aim for your baby (or each of your babies) at birth will be either to

(a) get immediate cord clamping OR

(b) hold the baby below the placenta for 60 seconds or more before the cord is clamped.

(a) or (b) is chosen randomly by a computer when staff phone the study centre. Medical information from you and your baby's stay in hospital will be collected from hospital records.
Later, we will phone you at home when your baby is about 6 and 12 months old for a 5 minute conversation to ask how your baby is doing and confirm your address. At about 18 months and again at 3 years the hospital will organize for you to bring your child in to a clinic to check how your baby sees, hears, talks, walks and thinks. These clinics take about 3 hours. We will collect this information for our study. To maintain contact with you please keep us updated if you move house or change phone number and let us have contact details of relatives or close friends not living with you.

5. Are there risks to me or my baby in taking part in this study?

It is important to understand that premature babies sometimes have serious complications. Some premature babies do not survive, some will develop problems with their lungs, eyes, intestine, and brain, and some will suffer from infections. These problems and their treatment will be explained to you if they arise. However, there is no evidence that taking part in the study will make these problems more likely or affect mother's health. Clamping the cord does not hurt the baby.

6. What happens if I or my baby suffers injury or complications as a result of the study?

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

7. Will I or my baby benefit from the study?

The study may or may not help your baby, but it may help improve treatment for preterm babies.

8. Will taking part in this study cost me anything?

No. Sydney University (the study sponsor) contributes towards the costs of additional paper work and staff time at the hospital for each baby enrolled. Parents are not paid for taking part. No one will make a financial profit from this study.

9. How will my confidentiality be protected?

Only hospital and study staff will know if your baby is in the study. We will also inform your GP, if you agree. No information about you or your baby (or babies) will be given out without your permission, except as required by law. We ask your consent to look at you and your baby's hospital medical records for research or analysis. Your study information may be seen by the study sponsor (Sydney University), or regulatory authorities as required by law, to check study procedures or data. Your study information will be stored securely and in the strictest confidence in the hospital and by the study sponsor, Sydney University. By signing the Consent Form, you allow personnel and authorities noted above to access this confidential information. If you withdraw your consent, the effective date will be when your withdrawal is received by the APTS study, and information collected before then will still be used for this project.

10. What happens with the results?

Study results will be provided to you, if you wish, by your study doctor when the trial is finished and data analysed. Your doctor will inform you about your own baby's results where relevant. If you give permission by signing the Consent Form, we plan to discuss or publish the results in national and international meetings and in medical journals. In any publication, you will not be identified.

11. Further Information or Any Problems

If you need more information or have problems about this study (for example, side effects), contact the principal investigator or study staff. The investigator responsible at Auckland Hospital is
Name: Katie Groom
Position: Consultant Maternal Fetal Medicine Subspecialist
Telephone: +64 9 367 0000 (switchboard) and request to speak to Katie Groom

12. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the multiregion ethics committee. If you have concerns or complaints about its conduct, contact an independent health and disability advocate who is nominated by the Human Research Ethics Committee to receive complaints from research participants. You should contact them on 0800 555 050 or fax 0800 27877678 or email Advocacy@hdc.org.nz.

Thank you for taking the time to consider being part of this study.
If you wish to take part in this study, please sign the attached consent form.
A copy of this signed information sheet is for you to keep.

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Request for interpreter

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

- I have read and I understand the information sheet dated 5/5/2014 for volunteers taking part in the study. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my health care, nor the health care of my baby.
- I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.
- I understand the compensation provisions for this study.
- I have had time to consider whether to take part in the study.
- I know who to contact if I have any questions about the study in general.

I agree to an approved auditor appointed by the ethics committee or the regulatory authority or their approved representative and approved by the ethics committee reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

Yes No

I wish to receive a copy of the results

Yes No

I consent to my GP being informed of my participation in this research

Yes No

Participants should be advised that a significant delay may occur between data collection and publication of the results.

I …… (*full name*)

of ……..(address)

hereby consent that I and my baby may take part in this study.

Date:	
Parent Signature:	
Full names of researchers:	
Contact phone number for researchers:	
Project explained by:	
Project role:	
Signature:	
Date:	

Notes:

Copies for
- parent
- research team
- maternal notes
- baby notes