PARTICIPANT INFORMATION SHEET

TITLE: Effect of breathing support during delayed cord clamping (DCC) for very preterm infants.

Short title: The ABC study

PRINCIPAL INVESTIGATOR
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Your preterm baby is invited to take part in this study. There is no obligation for your baby to take part and your baby’s care will not be different if you choose not to take part.

Background Information
Preterm babies and especially those born less than 31 week gestation are vulnerable and often need a blood transfusion as part of their care. We know that blood transfusions have risks. To help prevent blood transfusions, the practice of allowing up to a minute before the umbilical cord is clamped (delayed cord clamping) has been widely studied and is recommended in many hospitals including our own. By allowing time before the cord is clamped, blood flows from the placenta to increase baby’s blood volume. Babies that breathe before the cord is clamped receive more blood from the placenta than those that don’t breathe. The usual standard practice is to wait up to a minute before clamping the cord. This is the case whether baby is breathing or not. Once the cord is clamped, if the baby is still not breathing or has a low heart rate, the attending staff would provide breathing support. In this study we plan to carry out all the standard procedures but also provide breathing support if needed to one group of babies while the cord is still attached. Not only could this reduce the need for blood transfusions but may also help the blood flow in the lungs and brain to be more stable in the early period after birth.

Aim
The aim of this study is to determine if adding breathing support before the cord is clamped will prevent some blood transfusions and improve hospital outcomes for premature babies.

What happens during the study?
Most preterm babies born in this hospital receive delayed cord clamping as part of standard best practice. If your baby is breathing before the cord is clamped, the cord will be clamped at 45 sec (standard care). If your baby is not breathing regularly but appears in good condition before the cord is clamped, half of the babies will get breathing support from 20 -50sec while delayed cord clamping is taking place and the other half will complete the 50sec of delayed cord clamping and then get breathing support if needed. Our current usual practice for babies who are not breathing during delayed cord clamping is to watch the baby carefully but allow the delayed cord clamping to take place.
Which treatment will your baby get and for how long?
Whether your baby is in the group that gets breathing support before the cord is clamped will be decided at random. This is like tossing a coin to decide which group they are in. Neither parents nor staff will be able to decide which group your baby will go into. If baby’s condition is thought not to be satisfactory before the cord is clamped, the delayed cord clamping would be stopped early (also in keeping with our usual practice). At times the umbilical cord is too short to allow us to give breathing support and if this is the case your baby will get standard practice without breathing support.

Is there a benefit?
We suspect that babies who receive breathing support before the cord is clamped may not need as many blood transfusions and may have fewer complications during the hospital stay. In particular, there is potential to reduce the risk of brain bleeding and severe lung disease.

Is it safe?
We do not anticipate any risk to your baby from entering this study. We will work with the midwife and/or the obstetrician to keep the field sterile if there is a caesarean birth and to keep baby warm during the procedure (a sterile plastic warp is used as part of routine care).

Compensation
In the unlikely event of a physical injury to your baby as a result of participation in this study, you may be covered by ACC. ACC cover is not automatic, and your case would need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If your claim is accepted by ACC, you still may not get any compensation. This depends on factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses. 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.

Blood Tests
No additional blood tests will be taken from your baby should you decide to join this study.

Taking part in the study
To take part in this study the research team will collect information about your baby’s condition at birth and admission to the neonatal care unit. Information from the first heart scan and progress will be collected. Information from baby’s follow up examination at 2 years will also be collected.

Confidentially
No material which could personally identify you or your baby will be used when we report results of this study. Paper records will be kept in a locked filing cabinet in the clinical nurse specialist office and computer data is password protected and will only be available to the investigators.
Records are kept for 26 years then destroyed (shredded) or deleted from the computer. Hospital records for your baby will also be used to provide information for the study.

Other Information

- You can get more information about the study from investigators - Elizabeth Nevill, Dr Mike Meyer, Dr Lindsay Mildenhall, Jonathan Barrett, Dr Athol Johnson, or the research nurse.
- If you need an interpreter, one can be provided and you may have a friend, family or whanau support (2760044 ext 8138) to help you understand more about the study.
- Parents/guardians may obtain results of the study if requested (on the consent form.) There is often a delay of around 1-2 years from the start of the study.
- If you have any questions or concerns about your rights as a participant in this study you may wish to contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act. Telephone (NZ Wide) 0800 555 050 Free Fax (NZ Wide) 0800 2787678 (0800 2 SUPPORT) Email (NZ Wide) advocacy@hdc.org.nz

Please feel free to contact the researchers if you have any questions about this study.
CONSENT FORM

PROJECT TITLE:  The ABC study (short title)

Request for Interpreter

<table>
<thead>
<tr>
<th>Language</th>
<th>Translation</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>I wish to have an interpreter</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Maaori</td>
<td>E Hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero</td>
<td>Ae</td>
<td>Kao</td>
</tr>
<tr>
<td>Samoan</td>
<td>Oute mana’o ia iai se fa’amatala upu.</td>
<td>Io</td>
<td>Leai</td>
</tr>
<tr>
<td>Tongan</td>
<td>Oku ou fiema’u ha fakatonulea</td>
<td>Io</td>
<td>Ikai</td>
</tr>
<tr>
<td>Cook Island</td>
<td>Ka inangoro au I tetai tangata uri reo</td>
<td>Ae</td>
<td>Kare</td>
</tr>
<tr>
<td>Niuean</td>
<td>Fia manako au ke fakaagoa e taha tagata fakahokohoko kupu</td>
<td>E</td>
<td>Nakai</td>
</tr>
<tr>
<td>Fijian</td>
<td>Au gadreva me dua e vakadewa vosa vei au</td>
<td>Io</td>
<td>Sega</td>
</tr>
<tr>
<td>Tokelaun</td>
<td>Ko au e fofou ki he tino fakaliliu te gagana Peletania kin a gagana o na</td>
<td>Ioe</td>
<td>Leai</td>
</tr>
</tbody>
</table>

I/we have been invited to participate with my/our baby in the Effect of breathing support during delayed cord clamping for preterm infants Study.

I/we have read and understood the Participation Information Sheet dated 18 August 2015 for volunteers taking part in the study. I/we have had the opportunity to discuss the study. I/we am/are satisfied with the answers I/we have been given.

I/we have had the opportunity to use whanau support or a friend to help me/us ask questions and understand the study.

I/ we understand that:

- Taking part in this study is voluntary (my/our choice)
- My/our baby and I/we can withdraw from the study at any time this will in no way affect my/our baby’s or my/our future health care in any way
- My/our participation in this study is confidential and that no material that could identify me/us or my/our baby will be used in any study reports
- Only one parents consent is required for my/our baby to take part in the study
I/we have had time to consider whether to take part

I/we know who to contact if I/we have any questions about the study and understand that at the end of the study I/we will be able to request information regarding which group my/our baby was in.

I/we agree to the research team having access to medical information and hospital records concerning the health of my/our child. YES/NO

I/we wish to receive a summary of the results of this study. YES/NO

I/we to my/our baby’s GP being informed of baby’s participation in this study. YES/NO

PROJECT TITLE: The ABC study

I/we consent to the participation of my/our baby, _____________________ in the study described above.

Parent’s Full Name: ______________________________

Signature of Parent: ______________________________ Date: ________________

Parent’s Full Name: ______________________________

Signature of Parent: ______________________________ Date: ________________

Investigators:

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Project explained by:

Name: ______________________________ Role: ______________________________

Signature of Researcher: __________________ Date: __________________________