

- long term health and development. These risks exist whether or not your baby is in the study.

Too much oxygen in the blood for long periods

- Can lead to an eye problem called retinopathy of prematurity (ROP). About 1 in 50 babies with ROP become blind
- May damage the brain cells
- May contribute to chronic lung disease

Too little oxygen in the blood for long periods

- may damage the brain cells and lead to developmental problems
- may raise blood pressure in the lungs and contribute to chronic lung disease

- If your doctor was sure that one of the oxygen targets was better than the other (for whatever reason) your baby would not be asked to join this study.
- **The care and welfare of your baby is our utmost important priority at all times.**
- An independent group of experts will review the progress of the study and if a result comes out that one oxygen saturation range is clearly better than the other the study will be stopped.
- This study will increase medical knowledge and may improve the outcome for premature babies in future, but it may not directly benefit your baby.

Confidentiality

Any study information that can identify you or your child will be confidential. It would only be disclosed with your permission or if required by law.

Only people involved in the study and other authorised persons will have access to the trial data and the baby's medical records.

Study data will be stored at the hospital and at the Coordinating Centre at The University of Sydney for at least 23 years. Participants will not be identified in any publication.

Participation is Voluntary

If you decide to permit your child to participate, you are free to withdraw your consent and to discontinue your child's participation at any time, by contacting **<investigator name>**, whose contact details are listed below.

If you don't want your child to take part, or if you decide to withdraw your baby during the study treatment, this will not affect your baby's medical treatment or your relationship with medical staff at the Hospital.

However, if you do withdraw, we will ask your permission to follow your baby's progress to 2 years old.

With your consent, we may also keep track of your baby by the Health Insurance Commission Medicare database. However you can withdraw this permission as well.

If you choose not to take part in the study, your baby will receive oxygen by the nursery's current guidelines.

CONTACT DETAILS:

Which Oxygen saturation level should we use for very premature infants? A randomised controlled trial

Information for parents

Which oxygen saturation level should we use for very premature infants?

Benefits of Oxygen Saturation Targeting (BOOST II)

Thank you for taking time to read this when so much is happening to your baby. We know it is a difficult time for you. We would like to invite you and your baby to take part in the BOOST II research study.

Summary

- **You may either be at risk of delivering more than 12 weeks early; or Your baby has already been born less than 28 weeks gestation and is less than one day old**
- **Very premature babies need treatment with oxygen because their lungs are not fully developed**
- **We want to understand whether it's better for a baby's long term health to aim to keep the blood oxygen level at either 85-89% or 91-95%.**

What is the purpose of the study?

The purpose of this study is to understand which blood oxygen level (oxygen saturation) is better for very premature babies. Every premature baby's eyes, lungs or brain can be harmed by too much or too little oxygen in the blood for long periods.

- At present, doctors and nurses in different hospitals around the world usually aim to keep a very premature baby's blood oxygen saturation somewhere between 85% and 95%. We want to

find out if the lower or upper part of this range is better.

- This study has been very carefully designed to ensure that each baby receives the best possible care while we understand which oxygen saturation level is better.
- It is approved and funded by the National Health and Medical Research Council and is led by doctors who are experts in the care of very premature babies.
- It will enroll 1200 very premature babies from the major hospitals in Australia and is part of a worldwide study of about 5000 babies.

What does the study involve?

- Premature babies may be treated with extra oxygen in several ways: either through a ventilator, or through a face mask or nasal prongs, or into the incubator or a head box.
- We continuously monitor the oxygen in a baby with an oximeter (oxygen saturation monitor) on a hand or foot.
- The blood oxygen saturation usually goes up if babies breathe more oxygen and falls if they breathe less oxygen.
- Oximeters are used every day, and all day, in the care of every very premature baby.
- The oximeter is connected to a small sensor placed on the baby's hand or foot. The sensor shines a red light into the tissues and measures the oxygen saturation and heart rate every few seconds. This is painless and does not need blood samples [although blood samples are still needed as part of routine care to check other things, like carbon dioxide and blood chemistry].



These pictures show an oxygen sensor, which has been placed on the baby's foot and covered to keep out the light. The sensor lead is connected to an oximeter, which is not shown.

- Blood oxygen saturation changes every few seconds. It cannot be controlled exactly.

What happens in this study?

Babies who join the study will be allocated a study oximeter at random (like tossing a coin). The oximeters are all the same type but have been slightly altered to two different ranges.

The oximeters have been altered to read either slightly higher or slightly lower than the actual saturation:

- One type reads 88% - 92% when the oxygen saturation is actually 3% lower at 85% - 89%
- The other type reads 88% - 92% when the saturation is actually 3% higher at 91%-95%

The doctors and nurses will aim for an oxygen saturation of 88% - 92% with both types of oximeter

- Your baby will have an actual oxygen saturation target range of either 85% – 89% or 91% – 95%.
- The study monitor used with your baby is decided by chance, by a special computer programmed at the NHMRC Clinical Trials Centre in Sydney. Both levels are commonly used in premature babies.
- Neither you nor the doctors or nurses can choose or know which type of oximeter your baby gets.
- This type of masked randomised trial is the best way to find out which oxygen saturation is better for very premature babies in the future.
- Above or below the range of 85% - 95% each oximeter will always show the true oxygen saturation.
- For babies who do not need extra oxygen, the study oximeter will often read up to 100%. That's quite normal.
- It's very important that we find out how your baby is growing and developing at 2 years. When you go home, we'd like to keep in touch,

so we will record your contact details. It's important to tell us if they change



The pulse oximeter is a machine about the same size as a DVD player. It is kept on a shelf near the baby. This picture shows a display from a pulse oximeter. The baby's oxygen saturation reading is 91% and heart rate is 144

What information will be collected for this study?

- We will collect information from your baby's medical records about his or her progress and the treatment received while in hospital. Personal information will be kept confidential and stored securely. It will only be available to people who work for the study.
- When your baby is 2 years old we will arrange for you and your baby to be seen in the follow-up clinic at the hospital.
- During this visit we will assess mental and physical skills, vision, behaviour and general health.
- The visit should take around 2 hours and we will assist you with your travel expenses, if necessary.

What are the possible benefits and risks of taking part in the research?

- The main benefit is to help improve the care of future very premature babies.
- Babies are likely to benefit from the extra checks in the study.
- Too much or too little blood oxygen might affect