Questions families frequently ask about Research

What is a Research Study or Clinical Trial?

Clinical research is an integral part of our care of babies at Monash Newborn. Basically, clinical research is the application of scientific methods to answer questions about illnesses and how they can be treated. Findings from research guide us in delivering the best care we can for our patients.

Why should we be involved with Research?

The techniques and skills we have at our disposal today are based on advances made possible through clinical research. Many babies are alive today because of treatments and skills gained from past research. At Monash Newborn (as in other neonatal units in Australia) we rely on families joining our research projects to improve the care we deliver.

Do we have to take part in Research?

No, all participation in research is voluntary. If you are approached about a research study please feel free to ask as many questions as you need to satisfy yourselves that the project would be right for you and your baby. If you do not wish to take part, or change your mind about being involved, you may do so at any time without your baby's care being affected.

How do we know the Research is safe?

All our research projects have been reviewed by the senior doctors and nurses working in Monash Newborn as well as by Monash Health's independent Human Research and Ethics Committees, to ensure they are safe, fair and protective of patients' rights.

Who will talk to us about Research?

Our research nurses or a research team member will discuss the project with you, provide written information and answer any questions that you have.

If you would like more information about any of our research projects, please ask to speak to the

Consultant Neonatologist who is looking after your baby
via the hospital switchboard
on 9594 6666

Ms Emma Yeomans or Ms Kristy Elsayed who are our Research Nurses can also assist. They are contactable on telephone number 857 23743



Photograph courtesy of Olivia's mother



Information about Research studies and Clinical Trials

in

Monash Newborn



Our Research Studies and Clinical Trials

Monash Newborn, is an intensive care unit for newborn babies located at Monash Children's Hospital. Our aim is to provide the best possible care for babies who are ill, based on advances in clinical research.

Our research projects focus on a number of areas, such as improving respiratory and neurological outcomes of high risk infants, investigating the mechanisms of newborn brain injury and the development of cot-side monitoring as well as investigation of neuroprotective strategies. Monash Newborn also participates in research studies funded by the Australian National Health and Research Medical Council (NHMRC).

The following studies are currently underway in Monash Newborn and you may be approached by researchers to invite you to participate in them at various time during your baby's stay in the nursery.

We would like to thank you in advance for your time in reading this leaflet.

1. Studies conducted at the time of birth or soon after

Baby DUCC: The Baby Directed Umbilical Cord Cutting Study



Group: Babies who are born at 32 weeks or above, who need help with their breathing immediately after birth

Aim: To determine if it is better for babies who are not breathing well on their own to receive breathing support while still connected to their mother by the umbilical cord, and receiving blood from the placenta

The Neo-ICog Study



Group: Babies born before 29 weeks gestation

Aims: This study uses blood markers of immunity and blood clotting to see if they play a role in the health problems that affect preterm babies.

The OPTIMIST Trial

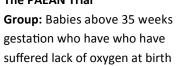


Group: Babies who are born

between 25 and 28 weeks gestation who are on CPAP.

Aim: This NHMRC funded study investigates if surfactant treatment while a baby is on CPAP can prevent need for mechanical ventilation

The PAEAN Trial



Aims: This NHMRC Trial aims to study if a medication called erythropoietin (Epo) can reduce the brain injury in babies

The PLUSS Trial



Group: Babies

born between 23 and 27 weeks gestation who are about to receive surfactant for their premature lung problems

Aims: To study if a steroid medication (Budesonide) given with the surfactant can help to prevent chronic lung disease

The IUGR - Early Cerebral Doppler study

Group: Growth restricted babies with concerns with Doppler scans in pregnancy, plus an equal number of matched well grown infants.

Aims: To study using Doppler ultrasound the blood flow in the brains of growth-restricted babies, and how they compare to their well grown counterparts.

2. Studies starting when babies are a few days old

The OVID Trial

Group: Premature babies under 32 weeks gestation with an open ductus arteriosus (PDA)

Aims: Comparing paracetamol (to current medication, indomethacin) as a new treatment for PDA

The PROTECT Trial



Group: Premature babies born under 29 weeks gestation who are being treated for infection (sepsis) or bowel infection like NEC

Aims: This NHMRC study is investigating if a medication called pentoxifylline can used to provide additional protection for the baby during these infections.

3. Studies starting when babies are many days or weeks old

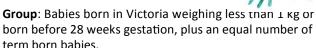
The PREBO Trial

Who: Babies born before 31 weeks gestation **Aims:** This project is to learn which tests (clinical and MRI) can be used at 30 weeks and 40 weeks to accurately identify which babies may have problems later in life.

"Does periodic breathing affect the outcome of preterm babies?" Study

Group: Babies born between 28-32 weeks gestation. **Aims:** To understand the effect of irregular breathing patterns on brain oxygen levels and outcome of preterm babies. Measurements will be taken while babies are sleeping. No needles or blood testing done.

Victorian Infant Collaborative Study (VICS)



Aims: This project will compare the development of the babies at 2 years of age, and possibly further into childhood.