Feeding Interventions Because of Respiratory Events (FIBRE) Study

AFFIX PATIENT LABEL

What is the FIBRE study about?

Doctors and nurses in the Newborn Care Unit in Gold Coast University Hospital are conducting a study to find out whether certain positions or feeding techniques reduce the number of breathing events in premature babies.

Premature babies are at risk of breathing events, including pauses in breathing and episodes of reduced oxygen levels and reduced heart rate. This commonly occurs while your baby is being fed. Nurses and doctors do a number of things to try and reduce these events, including changing the position of your baby, or giving the feed more slowly. No one really knows whether these things make a difference, or whether one position is better than another. The FIBRE study will aim to answer this question.

Why do premature babies have breathing events?

After they are born, babies must breathe continuously in order to get oxygen into their body. In some premature babies the parts of the brain and lungs that control breathing are not yet mature enough to allow regular breathing. This can cause periods of shallow breathing or pauses in breathing called apnoea. We know that your baby's stomach expands during feeds and this can affect breathing as well. Breathing events can be scary for many parents and if they happen frequently it can make your baby unwell, or may require some extra breathing support.

What feeding interventions might help?

Most of the time your baby is cared for lying flat on his/her back and feeds are given reasonably quickly through a feeding tube. Some people think that by trying different positions or by slowing down the feed we can reduce the number of breathing events. Techniques might include nursing your baby lying on his/her tummy, propping the cot up or giving the feed over a longer period of time, for example 45 minutes instead of the usual 5-10 minutes.

Why is the FIBRE study being done?

Many of these techniques are used in the Newborn Care Unit at GCUH and in other neonatal units, but we are uncertain whether one feeding intervention is better than the others. This study is designed to test whether these feeding techniques are effective in reducing breathing events. Answering this question will help doctors, nurses and midwives to make the right decisions when caring for premature babies in the future.

Which babies will be taking part in the FIBRE study?

The FIBRE study is looking at breathing events in ***premature babies*** and so we will only be enrolling babies who were less than 32 weeks at birth. In order to participate in the FIBRE study your babies will need to be at least 5 days old and meet a number of conditions, most of which will take longer to reach. These include:

- No longer requiring any support with breathing (low flow oxygen is okay)
- Receiving all his/her feed by tube into the stomach for the last 5 days
- Having feeds 3 hourly for the last 2 days

We will be conducting the study before your baby is having any suck feeds because we do not want the study to interfere with your baby learning to breast or bottle feed.

What will happen if my baby is part of the FIBRE study?

If you agree for your baby to participate in this study we would look to start the research when your baby meets the criteria above. Your baby will then experience three different feeding conditions, each for 24 hours - so that's 3 days in total. The conditions are:

A. Your baby will be lying flat on his/her back and feeds will be given as normal through a feeding tube (24 hours)

B. Your baby will be lying on his/her tummy with the cot propped up, and feeds will be given as normal through a feeding tube (24 hours)

C. Your baby will be lying flat on his/her back, and the feed will be given more slowly (over 45min) through the feeding tube (24 hours)

The actual order of these conditions will be random, but every baby enrolled in the study will experience all three.

While your baby is enrolled in the study, we will measure his/her heart rate, oxygen levels and any pauses in breathing – such monitoring is used routinely in the Newborn Care Unit, so this won't require any extra tests. We will also place a sign in your baby's room to let staff know that your baby is enrolled in the study.

Will I be able to interact with my baby during the 3 days?

This study is examining the effect of baby positon during feeds. For this reason, we ask that (for the three days your baby is enrolled in the study) that you do not pick up or cuddle your baby during his/her feed or for the hour straight after the feed. Outside of this time, we do encourage parents, as usual, to participate in cares of their baby, including nappy changes, weighs and baths and kangaroo care / cuddles.

What will happen if we choose not to take part in the FIBRE study?

That's okay! Choosing not to participate in FIBRE will in no way affect how we care for your baby in the Newborn Care Unit. There are no immediate benefits to your baby in participating in the FIBRE study, but your participation will potentially benefit other babies in the future. If you choose not to participate we will support that decision and the quality of care that you and your baby receive will not be affected in any way.

What will happen to the results of the FIBRE study?

Once the results of the FIBRE study have been analysed we will aim to have these results published in a medical journal so that other doctors, nurses and midwives can use these results to help in the care of premature babies in the future. None of the information reported in the final study can be used to identify your baby, and the information collected about your baby will be kept strictly confidential. If you would like to know the results of the study you can leave contact details with the research team who can contact you to inform you of the findings.

How can I obtain further information?

When you have read this information, Chris Richmond, Pita Birch, or another member of the research team are happy to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact:

- Dr. Chris Richmond (christopher.richmond@health.qld.gov.au , via 0756873536)
- Dr. Pita Birch (pita.birch@health.qld.gov.au , via 0756873484)

What can I do if I have a complaint or a concern?

Any concerns or complains about the conduct of the study should be directed to the:

- HREC Secretary

  Gold Coast University Hospital

  1 Hospital Boulevard, Southport, QLD 4215

  Email: GCHEthics@health.qld.gov.au

Any complaint will be investigated promptly and you will be informed of the outcome.

FIBRE Research Team

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For More information: www.goldcoast.health.qld.gov.au

Write any questions here

Informed Parental Consent to Participate in the Feeding Interventions Because of Respiratory Events (FIBRE) Study

AFFIX PATIENT LABEL

I _____ parent/guardian

(name of parent or guardian)

consent to _____, my child/ward

(name of child)

participating in the Feeding Interventions Because of Respiratory Events (FIBRE) Study that is taking place in the Newborn Care Unit of the Gold Coast University Hospital

Parent/Carer Signature: _____ Witness: _____

Date:_____

I have had this study fully explained to me by _____

I have had an opportunity to read the information page about this trial and have had ample opportunity to ask and have answered any questions I have about the trial.

I understand the benefit and risks of taking part in this study and have had those fully explained to me in a language that I can understand.

I understand that participation in this study is entirely voluntary and that the care of my baby will be unaffected by whether I choose to participate or not

I understand and agree that any deidentified written or electronic data taken during this trial may be made and stored confidentially and may be referred to at a later date, for clinical purposes, audit, teaching and for any other Ethics Committee approved research.

I understand that this research has been approved by the Gold Coast Hospital and Health Human Research Ethics Committee.