Thank you for taking part in the MAGENTA Trial

We would like to invite you to enrol your baby in an additional study for babies in MAGENTA.

Background

Babies who are born preterm are at increased risk of a number of complications that include difficulties with breathing, infection and problems with feeding. Most of these problems will resolve on their own. However, some babies may have longer term problems in infancy and childhood, including difficulties with development and learning. This is often related to problems with brain development around the time of birth.

The MAGENTA trial is assessing whether magnesium sulphate given to women just before giving birth between 30 and 34 weeks helps to protect their baby's brain and so increase the chance of the baby being born without complications and being free of learning and developmental disorders later in life.

We do not know how magnesium sulphate may lead to these beneficial effects. As a participant in the MAGENTA trial, we would like to invite you to consider also enrolling your baby in the MagNUM study. The MagNUM study is a unique opportunity for us to understand how magnesium sulphate may act to protect the baby's brain before birth. We hope to learn whether magnesium sulphate can reduce brain injury, particularly in the areas of the brain that control movement, learning and behaviour and how these changes in brain structure affect later development. We hope that this information will help to improve the health for babies at risk of being born preterm.

Is my baby eligible to participate?

Babies born to mothers enrolled in the MAGENTA Trial at the Auckland City Hospital are eligible to participate.

Participation is voluntary

If you do not wish to enrol your baby, this will not affect the normal care that your baby receives. You are also free to withdraw your baby at any time without affecting future treatment. Choosing not to take part in MagNUM does not affect your participation in the main MAGENTA trial. There is no payment for participation in this study.

What is involved for my baby if I give consent to participate?

If you provide written consent for this study, your baby will have an assessment when he or she is close to term equivalent age (greater than 37 weeks). We plan to assess the babies just before they go home from hospital whenever possible. However, if your baby is discharged home from hospital a little earlier, we will ask you to bring your baby to the Children's Research Centre at the Liggins Institute (close to Auckland City Hospital).

For the study assessment, babies will have:

- A Magnetic Resonance Imaging (MRI) scan. This will be done after your baby has been fed, wrapped and settled in a bean-bag pillow. No anaesthesia or sedation will be needed. This procedure takes approximately 45 minutes and in our experience, is tolerated very well by babies.

  Babies will have an oxygen saturation monitor, which displays both heart rate and oxygen saturation, attached during the MRI. The monitor will be constantly monitored by the research nurse. The parents will be able to stay with their baby during the MRI. The scan will be stopped if the baby becomes unsettled.

- A standard neurological assessment by a paediatrician, including checking the tone and reflexes in your baby's arms and legs. Babies will also be videotaped for assessment of spontaneous movements. This will provide new information about the link between neurological status, spontaneous movements and structure within the brain. This procedure will take about 20 minutes.

- Measures of growth – weight, length and head circumference.

As part of the MAGENTA trial, all children in the MagNUM study will also have a formal assessment at two years of age, corrected for prematurity, by a developmental paediatrician and psychologist.

Are there any risks?

There are no risks for the babies undergoing any of the above procedures for the MagNUM study. MRI's are being used increasingly in the standard care of babies born preterm who are unwell for diagnosis of problems. Neurological assessments and measures of growth are also routinely done with babies in the nursery.

If we find an unexpected problem on the MRI e.g. a small brain bleed, we will offer you an appointment with a paediatrician and arrange appropriate follow-up.

What happens to the information collected about my baby?

Your baby's health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the researchers involved in the trial. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel.

Only the researchers and study personnel at Auckland City Hospital will have access to your medical and contact details. Your name, date of birth and contact details and the names and contact details of your nominated contact people will be held securely at Auckland City Hospital.

No material which could personally identify you will be used in any reports on this study.

Who should I contact if I have further questions?

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the local researchers at Auckland City Hospital, Dr Jane Alsweiler.

If you have any questions or concerns about your rights as a participant in this research study you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act.
Phone: (NZ wide): 0800 555 050
Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)
Email (NZ wide): advocacy@hdc.org.nz

For Maori health support at the Auckland District Health Board or to discuss any concerns regarding this study, please contact the ADHB Maori Health Advisor, Maori Research Review Committee or the Research Office for more details researchoffice@adhb.govt.nz

What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

Statement of Approval

This study has received ethical approved from the Health and Disability Ethics Committee (HDEC) and the Auckland District Health Board Research Review Committee (Approval number LRS/12/06/021). The HDEC Administrator can be contacted on 0800 4 38447 if you have any questions or concerns.

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

Thank you for making the time to read about, and consider taking part in this study.

Investigators

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MagNUM

MAGNESIUM FOR NEUROPROTECTION: UNDERSTANDING MECHANISMS

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