We would like to invite you to participate in

The MAGENTA Study

a study looking at the use of magnesium sulphate given to women immediately prior to preterm birth to allow the best outcomes for their babies at 2 years of age.

Background

In Australia every year, many women like yourself, are at risk of giving birth preterm, because of complications for the mother and/or baby.

Your doctor will have discussed with you the risks for both you and your baby related to early birth. Babies that 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.

Magnesium sulphate has been recommended for use in women at risk of very preterm birth (less than 30 weeks gestation) to increase the chance of preterm babies being born without complications and being free of learning and developmental disorders later in life.

In a few studies, magnesium sulphate has been given to women at risk of preterm birth at gestational ages above 30 weeks, although the risk of cerebral palsy is less than for babies born at less than 30 weeks. It is not clear from the results available whether there is benefit.

This study is trying to determine whether the benefits of magnesium sulphate seen in babies born very preterm (before 30 weeks gestation), also apply to babies born at higher gestational ages.

Am I eligible to participate?

You are eligible to participate if:

- You are at risk of very preterm birth between 30 to 34 weeks' gestation where birth is planned or definitely expected within 24 hours
- You have a singleton or twin pregnancy
- You do not have any conditions that would otherwise prevent you from receiving magnesium sulphate

Participation is voluntary

If you do not wish to enrol it will not affect your care or that of your baby in any way. You are also free to withdraw at any time without affecting your baby's or your future treatment. There is no payment for participation in this study.

What is involved if I participate?

If you agree to take part in the study, you will be randomly entered by a special computer into one of the two treatment groups. You will have an equal chance of receiving magnesium sulphate or a placebo. A placebo is also called a "dummy" as it contains no active medication.

Neither you nor the people caring for you are able to choose the group you are allocated or will know which treatment group you belong to. This helps ensure that information obtained from the trial is as reliable as possible.
Whichever treatment group you are allocated to, your care in hospital will be provided by doctors and midwives. Your treatment involves an infusion pack given through an intravenous line over 30 minutes.

Regardless of the group you are allocated to, your care in hospital will be provided by doctors and midwives, and according to normal hospital care.

Are there any risks?

All medical procedures involve some risk of injury. In spite of all reasonable precautions, you may develop medical complications from participating in this study. The magnesium sulphate infusion may produce the following side-effects in approximately 50 % of women but they will subside after the infusion:

- a sense of warmth
- flushing
- sweating.
- nausea
- vomiting
- headache
- palpitations.

Serious side effects of depression of breathing and cardiac arrest have also been reported when larger amounts of magnesium sulphate have been given than will be used in this study. The infusion will be stopped if any serious side effects are experienced.

You will be monitored closely by your midwife during the infusion. If you experience any side-effects, or are worried about them, please inform your doctor or midwife. Please tell your doctor if you experience any new or unusual symptoms. There are some medical conditions with which magnesium sulphate should not be given. These include women with very low blood pressure, myasthenia gravis and renal failure.

For your baby, large amount of magnesium can cause reduced reflexes, poor sucking and rarely, respiratory depression requiring help with breathing. Babies exposed to magnesium sulphate before birth are monitored after birth in the nursery for any possible side effects.

Any of the above serious side effects for the mothers and babies in this trial are very unlikely as the dosage of magnesium sulphate used is quite small. There may also be risks associated with this trial that are presently unknown or unforeseeable.

Follow up of you and your child

Taking part in this study will involve your child being followed up until 2 years corrected age. Corrected age refers to the age a premature baby would be if he or she had been born on their due date.

You will be contacted at 6, 12 and 18 months by the trial research coordinator to confirm your contact details.

When your baby is 12 months corrected age we will ask you to complete a brief questionnaire about his or her development.

When your child turns 2 years corrected age an appointment will be made for him or her to see a developmental paediatrician and psychologist. At this follow-up appointment your child's health, development, behaviour, growth and blood pressure will be assessed and their hearing, vision and developmental milestones will be checked. These assessments will take approximately 2 hours.

There will be a questionnaire to complete about your child's development, behaviour, health and wellbeing. Together these questionnaires will take approximately 20 minutes to complete.

What happens to the information collected about me and my baby?

The case notes of you and your child will be accessed to gather information about the birth. Your information and that of your baby will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such breaches of confidentiality are rare; however we have an obligation to inform you of this possibility.

Version 1, 17/05/13

Study approval

This study has been approved by the Royal Children's Hospital HSD Research Ethics Committee.

More information?

For more detailed information please refer to the full participant information sheet.

More information can be obtained from the study clinicians (Professor Caroline Crowther, Associate Professor Philippa Middleton, Associate Professor Ross Haslam) by contacting them via the hospital switchboard (Ph: 8161 7000). The Study Coordinator, Pat Ashwood, can be contacted on 08 8161 7767.

Who should I contact if I have concerns about the conduct of this study?

Hospital specific information to be added

MAGENTA

MAGNESIUM SULPHATE AT 30 TO 34 WEEKS' GESTATIONAL AGE: NEUROPROTECTION TRIAL

Brief Participant Information Sheet

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