Queensland Government
Queensland Health

Master Participant Information Sheet and Consent Form

Clinical Trial

MAGENTA: Magnesium Sulphate at 30 to 34 weeks' **Ge**stational age: **N**europrotection **T**ri**a**l. .

Invitation
You are invited to take part in the MAGENTA trial, a research study that is looking at whether giving magnesium sulphate, compared with placebo, to women immediately prior to preterm birth between 30 and 34 weeks' gestation, reduces the risk of death or cerebral palsy in their children at 2 years' corrected age.

Site contact details:

These details will be completed by the sites for submission to their site Research Governance Officers (RGO's).

MAGENTA is a large multicentre collaborative study coordinated by Australian researchers:

Prof Caroline Crowther, Mrs Philippa Middleton, A/Prof Dominic Wilkinson and A/Prof Ross Haslam from the University of Adelaide and the Women's & Children's Hospital, Adelaide.

Contact details: MAGENTA Coordinating Centre at The University of Adelaide
Phone: (08) 8161 7767 Email: magenta@adelaide.edu.au

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'
Your doctor will have discussed with you the risks for both you and your baby related to early birth. Babies born preterm are at risk of a number of possible complications, including admission to the neonatal intensive care unit, difficulties with breathing, risk of infection, difficulties with feeding, and many others. Some of these problems will resolve on their own, but some may be associated with longer-term problems in early childhood, including difficulties with development, learning and cerebral palsy. Cerebral palsy is a condition where there may be problems related to movement and learning, and can be associated with long-term disability for the child.

Results from previous studies have shown that magnesium sulphate is effective in helping to protect the brains of preterm babies. This research has led to the current recommendations that magnesium sulphate be given to women likely to give birth very preterm *at less than 30 weeks'* gestation to increase the chance of their babies surviving free of cerebral palsy.

In a few studies, magnesium sulphate has also been given to women at risk of preterm birth at gestational ages *above 30 weeks*, however it is not clear from the results whether there is a benefit for the babies in helping them survive and develop normally into childhood.

The MAGENTA trial aims to determine whether magnesium sulphate, compared with placebo, given to women immediately prior to preterm birth between 30 and 34 weeks' gestation increases the chance of babies surviving and being healthy long-term. The main outcome of interest for this study is survival without cerebral palsy in the children at two years' corrected age.

Magnesium sulphate has been used safely for many years in pregnant women with severe preeclampsia and is now recommended for use in women at risk of preterm birth at less than 30 weeks.

The preparation of magnesium sulphate solution used for this trial is not an approved medication but it is made in Australia in a pharmaceutical manufacturing facility approved by the Therapeutic Goods Administration (TGA). The MAGENTA trial is also registered with the TGA.

There will be 1676 participants taking part in this research study.

The trial is being conducted by researchers from a number of organisations and is coordinated by the Discipline of Obstetrics & Gynaecology, The University of Adelaide at the Women's & Children's Hospital. A number of hospitals in Australia will be involved in recruitment for the trial.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because your doctor considers that you are very likely to give birth prematurely between 30 and 34 weeks gestation.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the care that you receive now or in the future and you will continue to receive the standard level of care from this hospital. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. 'What are the alternatives to participating in this study?'

If you decide not to participate in this trial, you will receive your care according to the local guidelines at your hospital. This currently does not involve the routine use of magnesium sulphate for women between 30-34 weeks gestation. Please discuss this with your doctor before deciding whether or not to take part in this research project.

5. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. This study will be conducted over the next 5 years. You and your baby will be involved until your baby reaches two years corrected age.

If you agree to participate in this trial, you will be randomly entered by a special computer into one of two treatment groups. This is like the flip of a coin. You will have an equal chance of being in the 'magnesium sulphate group' or the 'placebo group'. The placebo is a saline (salt water) solution and contains no active medication. The trial treatment solution is administered slowly through an intravenous infusion line over 30 minutes. Whichever treatment group you are allocated to, your care in hospital will be provided as normal by the doctors and midwives. In all other respects your care will be unchanged.

This trial is also 'double blind', meaning that neither you nor the people caring for you are able to choose the group you are allocated to or will know which treatment group you belong to (although, if the doctor needs to find out for medical reasons, he/she can do so). The magnesium sulphate and saline solutions look identical. The procedure of allocating participants randomly to one of two groups is known as 'randomisation' and helps ensure that the two groups are similar to start with and that the information obtained from the trial is as reliable as possible. MAGENTA is therefore known as a 'randomised trial'.

Your casenotes and your baby's casenotes will be accessed by members of the study team to collect the information required for the study about your pregnancy and your baby's birth.

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

You will be contacted by a member of the study team from the coordinating centre at The University of Adelaide by mail soon after your baby is discharged home from hospital and then again when your baby is 6, 12 and 18 months corrected age. You will be asked to confirm by mail, your contact details and the details of the contact people you provide when you enter the study. When your baby is 12 months corrected age, we will also ask you to complete a brief questionnaire about his or her development. At each of these times, a member of the study team will contact you by telephone if a response from you has not been received in the mail.

When your child turns two years' corrected age, you will be invited to attend an appointment for your child to see a developmental paediatrician and psychologist. They will assess your child's health, development, behaviour, growth and blood pressure. This assessment will include a vision and hearing test and a check on your child's developmental milestones. This assessment will take approximately 2 hours. There will be some questionnaires for you to complete about your child's development, behaviour and medical history. These questionnaires will take approximately 30 minutes in total to complete. You will be contacted by the follow-up coordinator at your recruitment hospital to organise this appointment. However, if you do not live close to this hospital, a member of the study team at the coordinating centre will telephone you to discuss a suitable alternative.'

6. 'How is this study being paid for?'

The study is funded by a grant from the National Health and Medical Research Council of Australia (NHMRC) and will be managed by The University of Adelaide. No money is paid directly to individual researchers.

7. Are there risks to me in taking part in this study?'

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 immediately 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.

8. 'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

9. 'Will I benefit from the study?'

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. 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 (30 to 34 weeks).

We cannot guarantee or promise that there will be any benefits from this research; however, if magnesium sulphate treatment has the same benefits seen in babies born before 30 weeks gestation, it is possible that your baby's long-term health and development may benefit from taking part in this trial.

10. 'Will taking part in this study cost me anything, and will I be paid?
Participation in this study is voluntary; if you do not wish to take part, it will not affect your care in any way. There will be no incentive or payment for participation in the trial. At the time of the 2 year follow−up assessment, participants may be reimbursed for their travel and other costs to enable them attend.

11. 'How will my confidentiality be protected?'
The people caring for you and your baby you will know that you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above and study personnel at your hospital and the MAGENTA coordinating centre 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 your Recruitment Hospital and at the coordinating centre at The University of Adelaide to enable conduct of the follow-up via mail and telephone calls.

12. 'What happens with the results?'
We plan to publish the results of this study in peer-reviewed journals and present at conferences or other professional forums.

In any publication, information will be presented in such a way that participants cannot be identified. Results of the study will also be provided to you by a letter written in lay language from the researchers at the time of publication.

13. 'What happens to my treatment when the study is finished?'
You will receive just the one infusion of the trial treatment solution. All of your care during the pregnancy and birth will be according to you hospitals standard guidelines.

14. 'What should I do if I want to discuss this study further before I decide?'
When you have read this information, a member of the study team at your hospital will discuss the study with you again and answer any queries you may have. You can also discuss it with the doctor and midwife providing your care. You will also be given the opportunity to discuss the study with your partner, other family members or friends if you wish. If you would like to know more at any stage, please do not hesitate to contact the MAGENTA Coordinating Centre by telephone (08 8161 7767) or by email (magenta@adelaide.edu.au).

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

These details will be completed by the sites for submission to their site Research Governance Officers (RGO's).

Thank you for taking the time to consider this important study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

MASTER PARTICIPANT CONSENT FORM

MAGENTA: Magnesium Sulphate at 30 to 34 weeks' **Ge**stational age: **N**europrotection **T**ri**a**l**.**

Investigators: Prof Caroline Crowther, Mrs Phillipa Middleton, A/Prof Dominic Wilkinson and A/Prof Ross Haslam

1. I,.....

   of.....
   agree to participate as a subject in the study described in the participant information statement set out above*.*

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the treatment, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Recruitment Hospital.

5. I give permission for MAGENTA trial research personnel to have access to my casenotes and my baby's casenotes.

6. I understand that identifiable data will be kept at the Recruitment Hospital and also sent to the MAGENTA Trial Coordinating Centre in Adelaide.

7. The Coordinating Centre will conduct the follow-up at 6 months, 1 year and 2 years corrected age.

8. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

9. I understand that if I have any questions relating to my participation in this research, I may contact _____ who will be happy to answer them.

10. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to: *details for submission to the site Research Governance Officer*.

SIGNED: …… Date: ……

NAME: ……..

WITNESS: …… Date: ……

MASTER PERSON RESPONSIBLE CONSENT FORM

Queensland Government
Queensland Health

MAGENTA: Magnesium Sulphate at 30 to 34 weeks' **Ge**stational age: **N**europrotection **T**ri**a**l**.**

Investigators: Prof Caroline Crowther, Mrs Phillipa Middleton, A/Prof Dominic Wilkinson and A/Prof Ross Haslam

1. I,.....

   of.....

   give my permission for …… *(insert participant's name)* to participate as a subject in the study described in the participant information statement set out above.

2. I acknowledge that I have read the participant information statement, which explains why the above named person has been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm that she might suffer as a result of participation and I have received satisfactory answers.

4. I understand that one can withdraw from the study at any time without prejudice to any relationship to the Recruitment Hospital.

5. I give permission for MAGENTA trial research personnel to have access to the casenotes of the above named person and her baby's casenotes.

6. I agree that research data gathered from the results of the study may be published, provided that no participant can be identified.

7. I understand that if I have any questions relating to participation in this research, I may contact _____ who will be happy to answer them.

8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to: *details for submission to the site Research Governance Officer.*

SIGNED: …… Date: ……

NAME: ……..

WITNESS: …… Date: ……

MAGENTA Trial: **Mag**nesium Sulphate at 30 to 34 weeks' **g**estational age: **N**europrotection **t**ri**a**l**.**

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the *University of Adelaide, _____ Hospital or my medical attendants*.

Signature: …… Date: ……

Please PRINT Name: ……

The section for Revocation of Consent should be forwarded to _____ at Department Obstetrics & Gynaecology, _____ Hospital