



## *Magnesium sulphate for treatment of pre-eclampsia: a trial to evaluate the effects on women and their babies*

# **Information Leaflet**

**T**hank you for reading this leaflet. This hospital, like many others in this country and around the world, is involved in a study to try and find out if magnesium sulphate is helpful for women with pre-eclampsia ('toxaemia'). This is an invitation to women, like yourself, who have pre-eclampsia to consider joining the study. If there is anything here you do not understand, or if you have other questions, your doctor or midwife will be able to discuss this with you or you can contact us directly (details overleaf).

### ***What is pre-eclampsia?***

**H**igh blood pressure is common during pregnancy, but this does not usually cause any problems. Some women have protein in their urine as well as high blood pressure, and this is called pre-eclampsia. Most women with pre-eclampsia feel quite well but high blood pressure and protein in the urine are detected at routine antenatal checks. This rarely happens before five or six months of pregnancy, and often it is just days or a couple of weeks before the baby is due. If the condition starts early in pregnancy it is often more serious, as pre-eclampsia will tend to get worse until after the birth. It always disappears quite soon after delivery.

**O**ccasionally women with pre-eclampsia have problems in their liver, kidneys, or blood clotting system. A few (about 1 in every 2000 pregnant women) will have a fit, and this is known as eclampsia. When this happens the woman usually needs careful nursing in hospital, and sometimes intensive care. The afterbirth (placenta) can also be damaged in pre-eclampsia. This may reduce the blood supply to the baby, which can prevent the baby from growing normally and sometimes leads to labour starting too early. If this happens the baby may need intensive care and will be more likely to have breathing problems, feeding difficulties or long term development problems.

**T**he cause of pre-eclampsia is not known, but it seems to be due to a problem in the placenta which we do not fully understand yet.

### ***Why use magnesium sulphate?***

**O**nce a woman has a fit (eclampsia) we know from recent research that magnesium sulphate is the best treatment to stop her having any more. Some doctors also give magnesium sulphate to women with pre-eclampsia, hoping that it will stop them having a fit and prevent some of the other problems of pre-eclampsia. For example, magnesium sulphate may help the woman's kidneys to work better and may help prevent the baby from being born too early. There is very little useful research into whether magnesium sulphate really is the best treatment. Although one study has suggested that it might be good for the women, this was not conclusive and gave little information about the effects for the baby.

### ***How is magnesium sulphate used?***

**M**agnesium sulphate is given first as an injection into a vein, often on the back of the hand or in the arm. Treatment is usually continued for 24 hours either by putting the drug into a drip, or by regular injections into the muscle. Because the body gets rid of magnesium sulphate through the kidneys, the amount of urine is also measured. If the amount is small the woman may need less magnesium sulphate. Very rarely if too much magnesium sulphate is given it can cause a temporary muscle weakness, which can lead to breathing problems. To stop this happening reflexes and breathing rate are checked regularly. Sometimes there are side effects of magnesium sulphate. These can include nausea or vomiting, thirst, drowsiness and confusion, but they all disappear when treatment is stopped.

### ***The Magpie Trial***

**T**his study is to try and find out whether magnesium sulphate stops women with pre-eclampsia having a fit. It will also test whether there are any immediate or future benefits of this treatment for the woman or the baby, and whether

there are any important side effects. To do this, half the women in the study will be given a magnesium sulphate solution, and the other half will be given a similar solution without magnesium sulphate (a placebo). If you decide to join the study which treatment you get will be decided randomly, rather like tossing a coin. This is so that magnesium sulphate can be tested fairly. Neither you, your doctor, nor your midwife will know if you are getting magnesium sulphate or placebo. In case your doctor needs to know, the information will be easily available by telephoning Oxford.

**Y**our care will not be affected in any other way. There will be no extra hospital tests for either you or your baby. All the information for the study will be collected from the hospital notes, it will be confidential and used only by the researchers in the trial. We plan to follow up some of the women, and their babies when they are older, to find out how they are. This means that if you agree to take part in the Magpie Trial we may write to you later.

### **Your decision**

**Y**ou may want to think a bit more about whether to take part, and discuss it with your partner or someone else. If you agree to join the study, it is important to start the treatment soon. You

can change your mind at any time if you wish to by asking your doctor or midwife to stop the treatment, but we would still like to be able to contact you later if necessary. If you do decide to join the study we will tell your GP that you are taking part and send him details about the Magpie Trial.

### **If you decide not to join**

**W**hatever your decision, it will not affect any other aspect of your care.

### **If you need more information**

**I**f you would like more information about this study, please ask your doctor or midwife, or contact the Magpie Trial Co-ordinating Centre (see back page).

If you have any comments or suggestions on how this leaflet could be improved, please send them to us.

Name of your local contact person:.....Tel: .....

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**Thank you**