



*Headed notepaper from XXX Hospital*

## **PATIENT INFORMATION SHEET FOR THE 3Mg STUDY**

(Is magnesium sulphate, in addition to standard treatment, effective in patients with an asthma attack?)

You are being invited to take part in a research study that is organised by the University of Sheffield and undertaken at XXX Hospital. Before you decide it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

### **What is the purpose of the study?**

The purpose of the study is to find out whether treating an asthma attack with magnesium sulphate relieves symptoms of breathlessness and reduces the chances that people with acute asthma will need to be admitted to hospital.

Magnesium sulphate has been used to treat asthma attacks for several years. It can be given either as an infusion into a vein or by being inhaled using a nebuliser. We know that treatment with magnesium sulphate can improve the results of breathing tests, but we do not yet know whether it improves patient's symptoms of breathlessness or reduces their chances of needing hospital admission. We also do not know whether it works better by infusion into a vein or inhaled through a nebuliser.

The study will compare standard treatment for asthma, with the addition of magnesium sulphate (given either into a vein or through a nebuliser), to standard treatment without magnesium sulphate.

### **Why have I been chosen?**

You have come to hospital with an asthma attack. The doctors treating you think that magnesium sulphate, if it is effective, may ease your symptoms of breathlessness and improve your chances of avoiding hospital admission.

### **Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

### **What will happen to me if I take part?**

If you agree to take part you will be given standard treatment for asthma with oxygen, nebulisers and steroids (prednisolone or hydrocortisone). In addition you will also be given an infusion of saline (salt and water) into a vein in your arm.

Along with the standard treatments you will be given one of the following three alternatives:

1. Magnesium sulphate added to the nebuliser but not the infusion.
2. Magnesium sulphate added to the infusion but not the nebuliser
3. Nothing added to either the infusion or the nebuliser (i.e. just standard treatment on it's own)

After you have been given the treatment we will monitor your symptoms for up to four hours. Depending upon your response to treatment the doctor will then advise whether you should be admitted to hospital or go home.

One month from now we will examine all of your hospital records and then send you a questionnaire in the post or telephone you asking you about your health, your recent use of health services and what you thought about the care you received.

You will be put into one of the three treatment groups by chance (randomly). Neither you, the staff nor the researchers will know which treatment you have been given (this is known as a “blind trial”). At the end of the trial the researchers will compare patients in the three groups and then reveal which treatment was which to find out which treatment helped patients most.

If it may affect your care then the doctors treating you can find out which treatment you have been given.

### **What do I have to do?**

All the treatments will be given by the doctors and nurses. You will to need answer some questions and do a Peak Flow recording (breathing test) to monitor your progress, and then complete a questionnaire in one month's time.

### **Are there any side effects to treatment?**

Magnesium sulphate can cause feelings of nausea, vomiting, thirst or facial flushing, particularly when given through a vein. In rare cases overdose of magnesium sulphate can cause weakness, coma or heart problems. The doctors will monitor your heartbeat during treatment.

### **What are the possible benefits of taking part?**

We cannot promise that the study will help you but doing the study may help to improve the treatment of people with an asthma attack.

### **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Sheffield or XXX Hospital but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **Will my taking part in the study be kept confidential?**

We will inform your GP that you have taken part in this study. We will record information about your treatment over the next few hours and a member of the research team will record information from your hospital notes and computer records in one month's time. All information that is collected about you during the course of this study will be kept strictly confidential. The information will be stored in a secure area of the hospital. A copy of the information will be sent to the University of Sheffield where it will be stored in a secure area and also kept as a password-protected computer file, both of which can only be accessed by the research team and regulatory authorities. We will destroy all identifiable information five years after the end of the study. An anonymised copy of the computer file (with any details that might identify you removed) will be retained and made available to other researchers for use in future studies.

### **What will happen if I don't want to carry on with the study?**

You can withdraw from the study at any time. We will need to keep the information you have given up to the time you withdraw but will not collect any new information or send you the questionnaire.

### **What will happen to the results of the research study?**

We will publish the results in a scientific journal and produce a report that is freely available to anyone who wishes to read it. You will not be personally identified in any report or publication we produce. Please contact us using the details below if you would like to see a summary of the results when the trial is completed.

### **Who is organising and funding the research?**

The research is organised by the University of Sheffield and funded by the Department of Health.

### **Who has reviewed the study?**

This study was given a favourable ethical opinion for conduct in the NHS by the XXX Research Ethics Committee.

### **Further information can be obtained from:** Prof SW Goodacre

Medical Care Research Unit  
University of Sheffield  
Regent Court, 30 Regent Street  
Sheffield S1 4DA  
0114 222 0842, [s.goodacre@sheffield.ac.uk](mailto:s.goodacre@sheffield.ac.uk)