

## **Information about a research study to look at the effect of Magnesium Sulphate for patients at risk of Wernicke Korsakoff Syndrome (WKS)**

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

### **What is Wernicke-Korsakoff Syndrome (WKS)?**

Wernicke-Korsakoff Syndrome (WKS) is a condition caused by a lack of thiamine (vitamin B1). As thiamine helps brain cells to produce energy from sugar, low levels of thiamine mean that the brain cells are unable to generate enough energy to work properly and this can lead to developing WKS. The symptoms include loss of memory, poor balance and drowsiness.

WKS is most commonly caused by alcohol misuse, but can be caused by other conditions. In Accident and Emergency, we routinely give people at risk of WKS high-dose injections of thiamine(vitamin B1) into a vein with a medicine called Pabrinex.

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

Magnesium is a mineral which has many different actions in the body, one of which may be to enhance the response of the body to thiamine. Alcohol-dependent patients also often have low levels of magnesium. In this research study we would like to determine whether giving magnesium with thiamine is more effective than giving either thiamine or magnesium alone. We will determine if this is the case by taking blood samples to measure the activity of a metabolic enzyme whose activity is known to be increased by thiamine, called red cell transketolase.

### **Why have I been invited?**

We have invited you to take part in this research study as you have been assessed as being alcohol dependent or in alcohol withdrawal. Therefore you may have low levels of thiamine and, or magnesium. Usually we would give you a medicine called Pabrinex as part of your routine care. This is why we are inviting you to take part.

We hope to involve 120 patients in this study.

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

No, you do not have to take part and it is up to you to decide. We will describe the research study and go through this information sheet, which we will then give to you to keep, and give you some time to make your decision. You can discuss this with family or friends. If you wish to take part we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive or your future treatment.

## **What would taking part involve?**

If you agree to take part, the study will take place whilst you are in the Accident and Emergency department and will involve 3 parts over 2-3 hours.

### **Part 1:**

We will:

- confirm that you meet the criteria to take part in the research study
- ask about your medical history,
- give you a physical examination. This will include a pregnancy test in women who may become pregnant.
- take a blood sample (17 ml, approximately 8 teaspoons) for both routine tests and for additional study specific tests which will include measuring the level of vitamins and minerals in your body, as well as of the activity of the enzyme red cell transketolase.

### **Part 2:**

We will then randomly allocate you (by chance, like the toss of a coin) to one of three groups. Each group will receive the following

Group 1- standard treatment with Pabrinex

Group 2 - Pabrinex (standard treatment) plus magnesium sulphate at the same time

Group 3- Magnesium sulphate followed by Pabrinex (standard treatment) about 2 hours later

All of these treatments are given as an injection into the vein lasting approximately 30 minutes.

### **Part 3:**

We will take a second blood sample approximately 2 hours after giving you treatment. However, if you are allocated to Group 3 we will then give you Pabrinex i.e. after taking the second blood sample.

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

We do not know if taking part in this research study will be of benefit, but the information we obtain will be used to determine whether a larger study measuring clinical outcomes would be appropriate.

## **Are there any risks in taking part?**

Blood sampling can cause some discomfort, and sometimes leave a bruise. In this research study we will minimise these effects by collecting blood samples for the study at the same time as routine blood samples, and use staff trained in these procedures.

If you are allocated to Group 3 the administration of Pabrinex (standard treatment) will be delayed for approximately 2 hours. There is no indication that this short delay will have any effect on patients in this group as the treatment is for low levels of thiamine which have developed over a much longer time (weeks to months).

Participation in the study will not delay treatment for alcohol withdrawal (with Diazepam type medication) in any way.

As with all medicines, magnesium can cause side effects but not everyone gets them. Side effects with magnesium most often occur when too much magnesium is administered but this is unlikely to happen in this study as you will only receive a single dose of magnesium. Other side effects include an allergic reaction. We will monitor you during and after the injection in Accident and Emergency.

## **Can I take part in this study if I am pregnant or breastfeeding?**

No. Magnesium may affect a developing or new born baby therefore anyone who is pregnant or breast-feeding will not be able to take part in the study.

## **What will happen to the blood samples I give?**

The samples you give will be analysed in NHS Greater Glasgow and Clyde laboratories. We will destroy these samples three months after completion of the study.

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

All information collected about you during the course of the research will be kept strictly confidential. We will remove your name and address from any information that leaves the hospital so that you cannot be recognised from it.

If you consent to take part in the research, we might need to use parts of your medical records for purposes of analysing the results. Members of the Ethics Committees, Regulatory

Authorities and staff from NHS Greater Glasgow and Clyde may also review your medical records, where this relates to your taking part in the study, to ensure the proper conduct of the study. We will not use your records for any other purpose or disclose these to anyone else without your permission.

By agreeing to take part in this study, and signing the consent form you consent to Members of the Ethics Committees, Regulatory Authorities and staff from NHS Greater Glasgow and Clyde to have access to you medical records for this purpose.

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

This study is sponsored by NHS Greater Glasgow and Clyde who will be liable for negligent harm caused by the design of the trial. NHS indemnity is provided under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements.

If you have concerns about the research study, you should ask to speak to Dr Donogh Maguire on 0141 211 4294.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure.

Phone: 0141 201 4500 (for complaints only)

E-mail: [complaints@ggc.scot.nhs.uk](mailto:complaints@ggc.scot.nhs.uk)

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

It is likely the full results of the study will be published in a medical journal. We also hope to present these at national and international medical meetings. A summary of the study findings in lay terms will be made available if you would like it. All data will be anonymous??

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

This study has been reviewed and approved by the West of Scotland NHS Research Ethics Committee 3 to confirm that this study has considered the 'rights and protection of patients' health. In addition, the study has been reviewed by the Research and Development Department of NHS Greater Glasgow and Clyde.

### **Who is funding this study?**

This study is supported by the Accident and Emergency and Biochemistry Departments, Glasgow Royal Infirmary, NHS Greater Glasgow and Clyde

### **Contact for further information**

For further information about this study please contact Dr Donogh Maguire on 0141 211 4294.

If you would like independent advice regarding this study you can contact Dr Ewan Forrest on 0141 232 0734.

Finally, thank you for taking the time to read this information leaflet and considering taking part in the study. If you wish to take part in the study we will give you a copy of this to keep and ask you to sign a consent form.