

## **INFORMATION SHEET FOR PATIENTS**

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### **The Stroke Oxygen Study**

#### **A randomised controlled study of routine oxygen treatment after acute stroke**

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

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

The purpose of this study is to examine whether giving oxygen supplementation routinely for the first three days to all stroke patients improves recovery and long term outcome. Currently oxygen treatment is used in patients who have breathing problems, but it is not given routinely to stroke patients who breathe normally. In stroke patients who breathe normally oxygen supplementation may help recovery, but it might be ineffective, or even delay recovery by restricting movement within bed and around the ward. Restricted mobility after the stroke may lead to chest infections and deep vein thrombosis.

This study will establish whether oxygen should be given routinely to all stroke patients or not. It will also establish whether oxygen should be given day and night, or at night only, and which patients will benefit most from routine oxygen supplementation.

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

This is a trial of oxygen treatment after stroke. You have been chosen because your doctors think that you may have had a stroke. You do not need oxygen treatment as you can breathe normally, but you may be given oxygen as part of this study should you decide to take part. Overall 6000 patients like you in the UK and world-wide will be asked to take part in this study.

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

No, it is up to you to decide whether or not to take part.

If you decide to take part, you will be given this information sheet to keep, and be asked to sign a consent form.

You are free to withdraw at any time without giving a reason.

If you decide not to take part in the study or to withdraw at any time this will not affect the standard of care you will receive.

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

The researcher will check your blood oxygen level using a clip on finger probe, ask you a few questions, and examine how the stroke has affected you. You will be given either standard treatment or one of 2 study treatments (see below). Blood pressure, temperature, heart rate and blood oxygen levels will be checked regularly for the first few days after the stroke, as is recommended clinical practice.

A member of the research team will examine you again after 1 week.

After 3, 6 and 12 months a member of the research team will contact you by post to find out how you are doing. If we are unable to contact you, we will check your address with your GP and ask the GP to let us know how well you have recovered from the stroke.

### **What is the treatment I will be given?**

You will be assigned at random to one of the 3 treatments shown here:

1. Oxygen supplementation for 3 days and nights in addition to usual clinical care
2. Oxygen supplementation for 3 nights in addition to usual clinical care
3. Usual clinical care (no routine oxygen therapy).

If during the course of the trial your doctors decide that you need oxygen treatment you will be given oxygen as appropriate for your clinical condition irrespective of which treatment group you are in.

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

After 3, 6, and 12 months we will ask you complete a questionnaire with questions about how the stroke has affected you and how you are getting on with day to day activities. This will take about 15 minutes to complete. We will provide you with a stamped addressed envelope in order for you to return the questionnaire to us.

If you have problems with completing the form a friend or relative may help you. Alternatively, we can help you complete the questionnaire either at a hospital clinic visit or a member of the research team can arrange a specific visit with you, at your convenience.

### **What are the possible disadvantages and risks of taking part?**

We do not expect you to experience any serious side effects. Oxygen treatment is used routinely in hospital for patients with breathing problems. Most stroke patients are given oxygen during ambulance transfer to hospital.

An earlier study of routine fixed dose oxygen supplementation has shown no benefit in unselected patients, and suggested the possibility that oxygen supplementation may increase mortality in a subgroup of patients with mild strokes. The Stroke Oxygen Study gives oxygen in a dose adjusted to the patient's blood oxygen concentration and continues treatment for longer (3 days rather than 24 hours). A pilot study for the Stroke Oxygen study has shown no evidence of harm in patients with mild strokes. Indeed, early recovery was better in the oxygen group, but at 6 months there was only

a very small, or no, benefit. A much larger study is needed to show with certainty whether oxygen does improve short and long-term recovery from stroke.

In some patients with severe and chronic breathing problems high doses of oxygen can slow down the breathing rate and cause unconsciousness. If you have chronic, severe breathing problems you will not be included in this trial.

You may consider the oxygen tubing uncomfortable, and being attached to the tubing may restrict your mobility.

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

We cannot promise that the study will help you, but the information we get might help improve the treatment of people with stroke.

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

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Medical research is covered for mishaps in the same way as for patients undergoing treatment in the National Health Service, i.e. compensation is only available if negligence occurs. Regardless of this, if you have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism will be available to you.

### **Will my clinical details be kept confidential?**

Medical notes will be examined during the study. All information which is collected about you during the course of the research will be kept strictly confidential.

Personal identifiable information will only be seen by members of the research team and by the data monitoring committee upon request. Information will be used to collect and verify your progress and to arrange for the follow up.

For all other purposes personally identifiable information will be removed and replaced by an anonymous identification number. All use of information within the United Kingdom is protected by the Data Protection Act 1998. If any information is to be released outside of the European Union (EU), data protection may be less reliable than within the EU.

If you agree, your GP and treating Consultant at the hospital will be notified of your participation in the trial. In the event that we are unable to obtain a 3, 6 or 12 month questionnaire from you, we may ask your GP how well you are getting on, provided you are happy for us to approach the GP in this way.

All identifiable information will be destroyed 10 years after completion of the trial.

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

The results of the study will be presented at scientific meetings and in medical and scientific journals. The findings may affect the way future stroke patients are treated and thus improve stroke treatment and recovery. You can obtain a copy of the study findings by contacting the principal investigator (address below).

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

This study is being co-ordinated by Dr C. Roffe from Keele University, North Staffordshire, UK and a group of researchers from different universities who are interested in the effect of oxygen on recovery after stroke (The Stroke Oxygen Study Group). The study is being sponsored by the North Staffordshire Combined Healthcare NHS Trust and supported by Keele University. This study is funded by the National Institute for Health Research. We are not being paid by any pharmaceutical companies to do this research.

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

The scientific merit of this study has been reviewed by experts in the field not involved in the project and by the North Staffordshire Research and Development Consortium. The ethical standards of the study have been approved by the North Staffordshire

Research Ethics Committee and the Local Research Ethics Committee of the hospital you are being treated in.

**What if I have any concerns?**

If you have any concerns or questions about this study or the way it has been carried out please contact the local principal investigator or the hospital complaints department.

**Who can I contact if I need further information?**

We are happy to answer any questions you may have relating to this study. Please ask me, the doctors or nurses on the ward, or the local principal investigator for further information.

**Thank you very much for taking the time to read this leaflet.**

**We will give you a copy of this leaflet and a copy of the signed consent form to keep.**

**Local Principal Investigator:**