

INFORMATION SHEET FOR LEGAL REPRESENTATIVES (RELATIVES AND CARERS)

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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 consider participation of your relative 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 your relative 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 patients who have had a stroke 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 has my relative been chosen?

This is a trial of oxygen treatment after stroke. Your relative has been chosen because your doctors think that he/she may have had a stroke. Your relative does not need oxygen treatment

as they can breathe normally, but oxygen may be given to them as part of the study. Overall 6000 patients like your relative in the UK and world-wide will be asked to take part in this study.

Does my relative have to take part?

No, it is up to you to decide whether or not your relative takes part.

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

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

If you decide your relative should not take part in the study, or if you or your relative would like to withdraw at any time this will not affect the standard of care your relative will receive.

What will happen to my relative if he/she takes part?

The researcher will check your relative's blood oxygen level using a clip on finger probe, ask your relative a few questions and examine how the stroke has affected him/her. He/she will be given either standard treatment or one of two 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 your relative again after 1 week.

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

What treatment will my relative be given?

Your relative will be assigned at random to one of 3 treatments:

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 an indication for oxygen treatment develops your relative will be given oxygen as appropriate for his/her clinical condition irrespective of which treatment group he/she is in.

What does my relative have to do?

After 3, 6, and 12 months we will ask your relative to complete a questionnaire with questions about how the stroke has affected him/her and how he/she is getting on with day to day activities. This will take about 15 minutes to complete. We will provide a stamped addressed envelope for returning the questionnaire to us.

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

What are the possible disadvantages and risks of taking part?

We do not expect your relative 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 small 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 form stroke.

In some patients with severe and chronic breathing problems high doses of oxygen can slow down the breathing rate and cause unconsciousness. If your relative has chronic, severe breathing problems he/she will not be included in this trial.

Your relative may consider the oxygen tubing uncomfortable, and being attached to the tubing may restrict his/her mobility.

What are the possible benefits of taking part?

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

What if there is a problem?

Any complaint your relative 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 or your relative 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 relative's clinical details be kept confidential?

Medical notes will be examined during the study. All information which is collected about your relative 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 relative's 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 relative's GP and treating Consultant at the hospital will be notified of his/her participation in the trial. In the event that we are unable to obtain a 3, 6 and 12 month questionnaire from your relative, we may ask your relative's GP how well your relative is getting on, provided you and your relative 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 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 your relative is being treated in.

What if my relative has any concerns?

If you or your relative 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: