Stroke Oxygen Study

A multi-centre, prospective, randomised, open, blinded-endpoint study to assess whether routine oxygen treatment in the first 72 hours after a stroke improves long-term outcome

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Trial Summary

Mild hypoxia is common in stroke patients and may have significant adverse effects on the ischaemic brain after stroke. The use of oxygen treatment is rapidly increasing in European stroke units. A questionnaire survey of UK stroke physicians showed that almost 50% of respondents would start oxygen supplementation after stroke at a level of oxygen saturation of 95% or above, which is well within the normal physiological range. Oxygen treatment is not without side effects. It impedes early mobilisation, could pose an infection risk, and may encourage the formation of toxic free radicals leading to further damage to the ischaemic brain. A study of routine oxygen supplementation given for 24 h at a rate of 3L/min published in 1999 (Ronning and Guldvog) has shown no benefit in unselected patients, and potential harm in patients with mild strokes. In the Stroke Oxygen Pilot Study [64 65] the flow rate of oxygen was lower (2 or 3 L/min dependent on baseline oxygen saturation) and treatment was continued for longer (72 hours). Neurological recovery at one week was better in the oxygen group and after correction for difference in baseline stroke severity and prognostic factors there was a trend to better outcome with oxygen at 6 months. In contrast to the earlier study by Ronning and Guldvog oxygen was as effective in mild as in severe strokes. These results are promising, but need confirmation in a larger study.

Before wider use of oxygen supplementation becomes established it is important to obtain better evidence on which patients benefit from such treatment. **SOS** is a large 'real life' trial which aims to produce reliable evidence on the balance of benefits and risks for different patient groups by randomising a large number of patients to routine oxygen supplementation or no routine oxygen treatment. The information on a few thousand patients randomised in **SOS** will help to guide the treatment of many thousands of future patients.

To make recruitment of a large, heterogeneous group of patients practicable procedures are kept simple, and eligibility is based on 'uncertainty'. Patients admitted to hospital with an acute stroke for whom there is substantial uncertainty whether or not they should receive oxygen or not are randomised to continuous oxygen treatment, nocturnal oxygen treatment or standard therapy (no routine oxygen) for 72 hours. Oxygen will be given at a rate of 2 or 3 litres/minute depending on baseline oxygen saturation. In this trial the extra work for collaborators is absolutely minimal. In addition to the randomisation form there is a one page baseline assessment and a brief clinical review at one week. Outcome data at 3, 6 and 12 months will be by a questionnaire sent to the patient by the trial centre. The success of **SOS** depends on the wholehearted support of doctors involved in acute stroke management. For this reason, publication of the final results will be in the names of all the collaborators, and not those of the principal investigators.

Trial Flow chart

Stroke Oxygen Study

Patient eligible for the study
Acute stroke
Less than 24 hours after hospital admission
No definite indications for oxygen treatment
No definite contraindications for oxygen treatment
No other serious medical condition limiting life expectancy to a few months or less

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Explain study
Obtain informed consent / assent

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Document baseline oxygen saturation
Complete randomisation form

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Log in to www.so2s.co.uk or phone 07740 37 28 52 to randomise the patient

Prescribe
Either or

No routine oxygen

Oxygen is not given routinely, but may be prescribed if definite clinical indications develop

Advise ward staff to monitor BP, HR, T, oxygen saturation at least 6 hourly

Oxygen per nasal cannula for 3 nights (21:00 – 07:00)

3L/min if oxygen saturation at baseline is ≤ 93%
2L/min if oxygen saturation at baseline is > 93%
Advise ward staff to monitor BP, HR, T, oxygen saturation at least 6 hourly

Continuous oxygen per nasal cannula for 72 h
3L/min if oxygen saturation at baseline is ≤ 93%
2L/min if oxygen saturation at baseline is > 93%
Advise ward staff to monitor BP, HR, T, oxygen saturation at least 6 hourly

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1 week post recruitment
Complete Assessment Form 1 and week 1 contact form

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3, 6 and 12 months post recruitment
SOS team to send questionnaires to the patient

Please contact Dr C. Roffe, Research Office, North Staffs. Combined Healthcare NHS Trust, Holly Lodge, 62 Queens Road, Hartshill, Stoke-on-Trent, ST4 7LH for randomisation, adverse events, or any queries daytime 0300 123 0891, nights and weekends 07740372852 (main) or 0773 4068408 (back up)

General information and Contacts

TRIAL MANAGEMENT COMMITTEE

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24 HOUR RANDOMISATION

http://www.so2s.co.uk

EMERGENCY CONTACT DETAILS

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SPONSOR DETAILS

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