ISRCTN12362720 https://doi.org/10.1186/ISRCTN12362720

The Stroke Oxygen Pilot Study: a randomised controlled pilot study of the effects of routine oxygen supplementation on functional outcome after acute stroke

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
30/01/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.so2s.co.uk/pilotstudy.shtml

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0158153698

Study information

Scientific Title
The Stroke Oxygen Pilot Study: a randomised controlled pilot study of the effects of routine oxygen supplementation on functional outcome after acute stroke

Acronym
SOS Pilot Study

Study objectives
The main hypothesis to be tested is that routine fixed dose oxygen treatment during the first three days after an acute stroke will reduce death and disability during the first six months after the stroke. It is likely that the proposed pilot study is too small to answer the research question, but it is necessary to perform this pilot trial in preparation for a larger multicentre study that will then answer the above research question.

The main objective of this pilot trial is to assess differences in main outcomes between treatment groups (stroke patients who received oxygen treatment compared to stroke patients who did not receive oxygen treatment). This will be used to calculate the study size for the planned multi-centre outcome trial.

As of 01/05/2008 this pilot study was updated. Any changes to this record can be see in the relevant field, under the update date of 01/05/2008. Please note that the anticipated end date of this trial has been changed as the trial has now finished recruiting. The previous anticipated end date of this trial was 01/11/2008.

The multicentre study to this trial is also in the ISRCTN Register, and can be found at http://www.controlled-trials.com/ISRCTN52416964.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 01/05/2008:
Ethics approval received from the Multicentre Research Ethics Committee on the 6th October 2004 (ref: 04/Q2604/73).

Study design
Prospective randomised open study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at http://www.so2s.co.uk/pilotstudy.shtml

Health condition(s) or problem(s) studied
Stroke

Interventions
300 patients with a clinical diagnosis of acute stroke will be recruited within 24 hours of hospital admission.

This is a prospective randomised open study of the effects of early routine fixed dose oxygen supplementation compared with standard care on functional outcome (death and disability) at six months after acute stroke. An open design was chosen because placebo treatment (room air) would have at least some of the potential side effects of active treatment (e.g. limitation of mobility and risk of infection) without having any beneficial effects and might therefore bias the results in favour of the treatment group. Patients will be randomised to one of two treatment groups:
1. Treatment group 1: no routine oxygen supplementation during the first three days of randomisation
2. Treatment group 2: oxygen per nasal cannula continuously (day and night) at a flow rate of 3 l /min if baseline oxygen saturation is less than 93% or at a rate of 2 l/min (if baseline oxygen saturation is greater than 93%) with humidification during the first three days after randomisation. Patients who develop definite indications or contra-indications for oxygen treatment during the trial will be treated according to clinical need, irrespective of study treatment allocation.

Blinding:
The main outcomes will be ascertained at six months by postal questionnaire. It is likely that participants will have forgotten which treatment group they were in six months after the intervention, and it is therefore unlikely that treatment allocation will bias their answers. We will assess whether patients remember their treatment allocation by including this as a question in the six-month assessment questionnaire.

Assessments:
Overnight pulse oximetry and day three assessment: in order to ascertain whether the prescribed oxygen supplementation effectively prevents hypoxia, pulse oximetry will be performed overnight on night two while the patient is receiving oxygen or no oxygen. We will also be able to quantify the time patients spent with an oxygen saturation level above the normal range. This is necessary to fine-tune the dosage schedule for the planned multicentre outcome study.

The day three assessment (Assessment Form 1) will document compliance with the trial treatment, relevant aspects of the patient's past medical history, and the stroke type (Oxfordshire Community Project Stroke Classification), and confirm completion of the overnight pulse oximetry. If incomplete, pulse oximetry will be repeated on night three of treatment.

The week one assessment (Assessment form 2) is designed to screen for potential adverse effects of oxygen and includes indicators of infection, stress (tachycardia and hypertension), behavioural disturbances, cognitive function, and neurological deterioration. If the patient is well enough to cooperate the researcher will discuss the 6 months assessment and find out the preferred contact(s) for mailing the questionnaire.

The month three assessment (Assessment Form 3) documents the length of stay in hospital, and discharge destination. The discharge address and the contact details of the GP are recorded in preparation for the 6 months follow-up. It will be completed using information from the HISS /CHIPS hospital computer system and patient notes.

The month six assessment (Assessment Form 4) will provide the main outcome (death and disability at six months) data for testing the trial hypothesis of the planned larger study. It consists of a questionnaire that will be sent to the patient's preferred contact address (if known) or the discharge address. Outcomes will be assessed using well-validated scales (Rankin, three-point Barthel, EuroQoL, the Nottingham Extended Activities of Daily Living Index).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oxygen

Primary outcome measure
Death and disability using the following measures:
1. Death and disability (Rankin Score greater than three) at six months
2. Scandinavian Stroke Scale at week one
3. Mortality up to six months
4. Rankin Score at six months
5. Nottingham EADL score at six months

Secondary outcome measures
Added as of 01/05/2008:
1. Potential side effects of oxygen treatment
2. Frequency of protocol violation
3. National Institutes of Health Stroke Scale (NIHSS)/Scandinavian Stroke Scale (SSS) at one week
4. Oxygen saturation while on treatment

To assess the feasibility of recruiting stroke patients within 24 hours of hospital admission.

Overall study start date
21/07/2004

Completion date
02/04/2008

Eligibility

Key inclusion criteria
Adult patients (either sex) will be eligible for trial inclusion if they were admitted with symptoms of an acute stroke within the preceding 24 h and if, in the doctor's opinion, there is no clear indication for and no clear contraindication against oxygen treatment (added as of 01/05/2008).

1. Identification:
All patients admitted to the University Hospital of North Staffordshire with an acute stroke will be eligible to be considered for trial inclusion. They will be identified as potential participants by a member of the research team or by staff in the Medical Admissions Unit, Accident and Emergency (A&E), or the Emergency Admission Unit.

2. Approach:
Potential participants will be approached by a member of the research team or the doctor admitting the patient. Because hypoxia is more likely to be detrimental early after the stroke, when the ischaemic penumbra either recovers or expands it is crucial to include patients as soon as possible after the stroke onset into the trial. Patients will therefore be approached as soon as they enter hospital via the Medical Assessment Unit or the Accident and Emergency department, or at the next earliest opportunity on a medical ward up to 24 hours after admission.

3. Recruitment:
The study will be explained to potential participants and they will be invited to take part. The patient will then be given an information leaflet. If he/she agrees to take part they will be recruited to the trial after informed consent has been given. If the patient does not disagree, but is incompetent to give fully informed consent, assent will be sought from the next of kin using the same procedure.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300 patients

Key exclusion criteria
Added as of 01/05/2008:
1. Patients who have recognised indications for oxygen treatment such as:
1.1. Oxygen saturation on air less than 90%
1.2. Hypoxia associated with acute left ventricular failure, severe pneumonia and pulmonary embolus
1.3. Chronic respiratory failure treated with long term oxygen at home
2. Recognised contra-indications to fixed dose oxygen treatment (2 - 3 l/min/vy nasal tubes):

type II respiratory failure (contra-indication to fixed dose oxygen as given in this trial)
3. The stroke is not the patient's main clinical problem: the patient has another serious life-threatening illness likely to lead to death within the next few months

Date of first enrolment
21/07/2004

Date of final enrolment
02/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Elderly Care Unit
Stoke-on-Trent
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ST4 6QG

Sponsor information

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Department of Health

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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Staffordshire Research and Development Consortium (UK) - North Staffordshire Combined Healthcare Trust

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Pilot study:	01/11/2005		Yes	No
Other publications	Conversion factor development:	01/11/2007		Yes	No
Results article	Comparative study:	01/11/2007		Yes	No
Results article	results	01/11/2011		Yes	No
Results article	results	03/06/2013		Yes	No