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The Stroke Oxygen Study: a multi-centre, prospective, randomised, open, blinded-endpoint study of routine oxygen treatment in the first 72 hours after a stroke

Submission date
19/06/2007

Recruitment status
No longer recruiting

Registration date
10/07/2007

Overall study status
Completed

Last Edited
03/04/2018

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[X] 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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

2006-003479-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/Q2604/109

Study information

Scientific Title
The Stroke Oxygen Study: a multi-centre, prospective, randomised, open, blinded-endpoint study of routine oxygen treatment in the first 72 hours after a stroke

Acronym
SO2S

Study objectives
Main hypothesis:
Fixed dose oxygen treatment during the first three days after an acute stroke improves outcome.

Secondary hypothesis:
Restricting oxygen supplementation to night time only is more effective than continuous supplementation.

The pilot study of this trial can be found at ISRCTN12362720 (http://www.isrctn.com/ISRCTN12362720).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Research Ethics Committee (Mellor House, Corporation Street, Stafford, ST16 3SR, UK), 31/10/2006, ref: 06/Q260/109. Protocol version 2 approved on 24/01/2007 and on 26/06/2008.

Study design
Multi-centre prospective randomised open blinded-endpoint study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

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

Health condition(s) or problem(s) studied
Stroke, cerebral infarct, intracerebral haemorrhage, cerebrovascular disease

Interventions
Treatment group 1: no routine oxygen supplementation during the first 72 hours after randomisation.
Treatment group 2: oxygen per nasal cannula overnight (21:00 - 7:00) at a flow rate of 3 L/min (if baseline oxygen saturation is 93% or below) or at a flow rate of 2 L/min (if baseline oxygen saturation is greater than 93%) during the first three nights after randomisation.
Treatment group 3: oxygen per nasal cannula continuously (day and night) at a flow rate of 3 L /min (if baseline oxygen saturation is 93% or below) or a flow rate of 2 L/min (if baseline oxygen saturation is greater than 93%) during the first 72 hours after randomisation.

All patients will have regular observations of vital signs (blood pressure, heart rate, temperature and oxygen saturation) as per the local protocol of the stroke unit, but at least six-hourly. Treatment of any abnormal findings will be independent of trial allocation. Patients who require oxygen or changes in the dose of oxygen for clinical reasons at any time of the trial will be given the concentration of oxygen they require.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Modified Rankin Scale score at 3 months

Secondary outcome measures
1. Secondary outcomes at 1 week:
1.1. Mortality
1.2. Number of patients with neurological deterioration (death or a greater than 4 point increase in the National Institutes of Health Stroke Scale [NIHSS])
1.3. Deaths
1.4. Highest oxygen saturation during the first 72 hours
1.5. Lowest oxygen saturation during the first 72 hours

2. Secondary outcomes at 3 months:
2.1. Mortality
2.2. Percentage of patients living at home
2.3. Ability to perform activities of daily living (Barthel index)
2.4. Quality of life (EuroQuol)
2.5. Extended Activities of Daily Living (Nottingham EADL score)

Overall study start date
20/04/2008

Completion date
01/11/2013

Eligibility

Key inclusion criteria
Adult patients (either sex) are eligible for trial inclusion if they were admitted with symptoms of an acute stroke within the preceding 24 hours, and if, in the doctors opinion, there is no clear indication for and no clear contraindication against oxygen treatment:
1. Potential indications for oxygen treatment could be:
1.1. Oxygen saturation on air less than 90%
1.2. Hypoxia associated with acute left ventricular failure
1.3. Severe pneumonia
1.4. Pulmonary embolus
1.5. Chronic respiratory failure patients treated with long term oxygen at home
2. Potential contraindications to fixed dose oxygen treatment could be:
2.1. Type 2 respiratory failure
2.2. Very severe hypoxia
3. Medical centres are eligible for participation in the study if they admit patients with acute stroke, are able to provide oxygen treatment and monitor oxygen saturation, and if there is a local researcher who will act as the principal investigator for the locality

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
6000

Key exclusion criteria
Patients will be excluded from the trial if:
1. The responsible doctor considers the patient to have definite indications for or contraindications to oxygen treatment at a rate of 2 - 3 L/min. The decision will be left to the responsible clinician
2. The stroke is not the main clinical problem
3. He/she has another serious life-threatening illness likely to lead to death within the next few months. This group of patients is excluded because it is unlikely that they are going to derive any benefit from the trial treatment

Date of first enrolment
20/04/2008

Date of final enrolment
01/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Infirmary
Stoke-on-Trent
United Kingdom
ST4 7LN

Sponsor information

Organisation
North Staffordshire Combined Healthcare NHS Trust (UK)

Sponsor details
Research & Development Department
North Staffordshire Combined Healthcare NHS Trust
Trust Headquarters
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Sponsor type
Hospital/treatment centre

Website
http://www.nsch-tr.wmids.nhs.uk/site/show_page.php3?page_id=1

ROR
https://ror.org/02d5d0r05

Funder(s)

Funder type
Government

Funder Name
North Staffordshire Combined Healthcare NHS Trust (UK)

Funder Name
Keele University

Alternative Name(s)
La Universidad de Keele

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	31/03/2014		Yes	No
Statistical Analysis Plan	statistical analysis plan	16/06/2014		No	No
Results article	results	26/09/2017		Yes	No
Results article	results	01/03/2018		Yes	No