

# 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

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<b>Registration date</b> 10/07/2007	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/04/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Christine Roffe

### Contact details

SOS STudy, Stroke Research, Medical Illustrations  
Royal Infirmary  
Prince's Road  
Hartshill  
Stoke-on-Trent  
United Kingdom  
ST4 7LN  
+44 (0)1782 555875  
[Christine.roffe@northstaffs.nhs.uk](mailto:Christine.roffe@northstaffs.nhs.uk)

## Additional identifiers

### Clinical Trials Information System (CTIS)

2006-003479-11

### Protocol serial number

## 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

### Study type(s)

Treatment

### 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(s)**

Modified Rankin Scale score at 3 months

## **Key secondary outcome(s)**

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)

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Royal Infirmary

Stoke-on-Trent

United Kingdom

ST4 7LN

# Sponsor information

## Organisation

North Staffordshire Combined Healthcare NHS Trust (UK)

## 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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	26/09/2017		Yes	No
<a href="#">Results article</a>	results	01/03/2018		Yes	No
<a href="#">Protocol article</a>	protocol	31/03/2014		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Statistical Analysis Plan</a>	statistical analysis plan	16/06/2014		No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes