

Identification sticker or Name <input type="text"/> Sex male / female DOB <input type="text"/> DD MM YYYY Unit No /Hiss No <input type="text"/>	<h2 style="margin: 0;">Stroke Oxygen Study</h2> <h3 style="margin: 0;">Randomisation Form</h3> Trial Centre name <input type="text"/> Investigator name <input type="text"/>
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STEP 1 ELIGIBILITY FOR TRIAL INCLUSION

Time since admission with a clinical diagnosis of stroke (WHO criteria) more than 24h	YES	NO
Time since stroke onset more than 48 h	YES	NO
Expected to die within 1 year from a non-stroke related illness	YES	NO
Definite indication for continuous oxygen treatment	YES	NO
Definite contraindication to continuous oxygen treatment	YES	NO

Please proceed to patient details if all answers to Q1 are **NO**

STEP 2 PATIENT DETAILS

Date and time of stroke onset dd-mm-yyyy hh:mm (24 h clock)

Oxygen given in the ambulance no / not known / yes

(for yes specify: 24% mask / 28% mask / 35% mask / 40% >40% mask / 2L/min via nasal cannula / 3L/min via nasal cannula / 4 L/min via nasal cannula/ >4l/min via nasal cannula)

Oxygen given after arrival in hospital no / not known / yes

(for yes specify: 24% mask / 28% mask / 35% mask / 40% >40% mask / 2L/min via nasal cannula / 3L/min via nasal cannula / 4 L/min via nasal cannula/ >4l/min via nasal cannula)

Medical History

Chronic obstructive airways disease or asthma [by history or from list of drugs]	YES	NO
Other chronic lung problem [e.g. kyphoscoliosis, thoracoplasty, pneumoconiosis]	YES	NO
Heart failure [by history, exam or >20 mg furosemide or equivalent per day]	YES	NO
Ischaemic heart disease [history of angina or MI or treatment with nitrates or nicorandil]	YES	NO
Atrial fibrillation	YES	NO

Glasgow Coma Scale (please circle one response in each row)

Eye opening	None (1)	To pain (2)	To speech (3)	Spontaneous (4)		
Motor Response	None (1)	Extension (2)	Abnormal flexion (3)	Withdrawal (4)	Localizes to pain (5)	Obeys commands (6)
Verbal resp.	None (1)	Incomprehensible (2)	Inappropriate (3)	Confused (4)	Oriented (5)	

STEP 3 PROGNOSTIC FACTORS (please circle the yes or no and complete oxygen saturation)

1.1 Age (no need to enter here, will be calculated from DOB and date of stroke)		
1.2 Living alone before the stroke	YES	NO
1.3 Independent in activities of daily living before the stroke	YES	NO
1.4 Normal verbal response to questions (e.g. verbal Glasgow coma Scale Score=5)	YES	NO
1.5 Able to lift the affected arm against gravity	YES	NO
1.6 Able to walk unaided	YES	NO
2. Oxygen treatment prior to randomisation (ambulance or emergency department)	YES	NO
3. Oxygen saturation on room air at randomisation	%	
4. Blood glucose (result of BM stick suffices)	mmol/l or g/dl	

STEP 4 NIH Stroke Scale

1a Level of Consciousness (LOC)	0	Alert – <i>keenly responsive</i>	
	1	Drowsy – <i>arousable by minor stimulation to obey, answer, or respond</i>	
	2	Stuporous – <i>requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped)</i>	
	3	Comatose – <i>responds only with reflex motor or autonomic effects or totally unresponsive, flaccid</i>	
1b LOC Questions	0	Answers both correctly	
	1	Answers one correctly	Patient is asked to state the month & his/her age
	2	Both incorrect or no reply	
1c LOC Commands	0	Obeys both correctly	
	1	Obeys one correctly	Patient is asked to open & close eyes, grip & release normal hand
	2	Both incorrect or no reply	
2. Best Gaze	0	Normal	
	1	Partial gaze palsy – <i>gaze is abnormal in one or both eyes, no forced deviation/total gaze paresis</i>	
	2	Forced deviation – <i>or total gaze paresis not overcome by oculocephalic manoeuvre</i>	
3. Visual Fields	0	No visual loss (or in coma)	
	1	Partial hemianopia	
	2	Complete hemianopia	
	3	Bilateral Hemianopia – <i>including cortical blindness</i>	
4. Facial Palsy	0	Normal	
	1	Minor - <i>flattened nasolabial fold, asymmetry on smiling</i>	
	2	Partial – <i>total or near total paralysis of lower face</i>	
	3	Complete - <i>absent facial movement in upper and lower face on one or both sides</i>	
5/6 Best Motor ARM		Right	Left
	0	0	No drift – <i>holds limb at 90 degrees for full 10 seconds</i>
	1	1	Drift - <i>drifts down but does not hit bed</i>
	2	2	Some effort against gravity
	3	3	No effort against gravity
	4	4	No movement
7/8. Best Motor LEG		Right	Left
	0	0	No drift – <i>holds limb at 45 degrees for full 5 seconds</i>
	1	1	Drift - <i>drifts down but does not hit bed</i>
	2	2	Some effort against gravity
	3	3	No effort against gravity
	4	4	No movement
9. Limb Ataxia	0	Absent (or in coma)	
	1	Present in 1 limb	
	2	Present in 2 or more limbs	
10. Sensory	0	Normal	
	1	Partial loss – <i>patient feels pinprick is less sharp or is dull on affected side</i>	
	2	Dense loss (or in coma) - <i>patient is unaware of being touched on face, arm, leg</i>	
11. Best Language	0	No dysphasia	
	1	Mild – moderate dysphasia <i>obvious loss of fluency or comprehension, without significant limitation on ideas expressed or form of expression. Makes conversation about provided material difficult or impossible, e.g. examiner can identify picture or naming card from patient's response.</i>	
	2	Severe dysphasia - <i>all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener who carries burden of communication. Examiner cannot identify materials provided from patient response</i>	
	3	Mute <i>no usable speech or auditory comprehension, or in coma.</i>	
12. Dysarthria	0	Normal articulation	
	1	Mild – moderate dysarthria - <i>patient slurs some words, can be understood with some difficulty.</i>	
	2	Unintelligible or worse - <i>speech is so slurred as to be unintelligible (absence of or out of proportion to dysphasia) or is mute/anarthric, or in coma</i>	
13. Neglect	0	No neglect (or in coma)	
	1	Partial neglect - <i>Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities</i>	
	2	Complete neglect - <i>Profound hemi-inattention or hemi-inattention to more than one modality. Does not recognise own hand or orients to only one side of space</i>	
Total:			

STEP 5 CONSENT

1. Fully informed consent	YES	NO
2. Patient does not disagree with trial	YES	NO
3. Consent from next of kin	YES	NO

Before randomisation either 1
OR 2 and 3 must be answered as YES

STEP 6 RANDOMISATION via <http://www.so2s.co.uk> or 01782 553369 (day) or 07740 37 28 59 (after hours)

Date and time of randomisation dd-mm-yyyy hh:mm (24 h clock)

Randomisation number Print Name _____ Sign and Date _____

Monitor oxygen saturation 30 minutes after the start of treatment and 6 hourly thereafter.

STEP 7 CONTACT preferred location for week 1 follow-up if no longer in hospital at that time

Clinic Home Other _____ Not applicable (severe stroke, unlikely to be discharged by one week)

Stroke Oxygen Study Week 1 (Assessment form)

Name Randomisation no

Home address: _____

Home telephone no: _____ NHS number

Has the patient died? yes / no Date of death DD MM YYYY

Please complete the Notification of Death Form (form 3) if the patient is deceased.

Has the patient had serious adverse events? If yes, please complete SAE form (form 4) yes / no

Oxygen administration for clinical indications during the 72 hour trial period:

- The patient was prescribed or received continuous oxygen for clinical indications
- The patient was not prescribed or given continuous oxygen for clinical reasons outside the trial treatment

Compliance with oxygen treatment as prescribed for this study:

- Oxygen prescribed for 3 nights and signed in the drug chart as instructed
- Oxygen prescribed for 3 nights, but not signed as instructed
(please explain _____)
- Oxygen prescribed for 72 hours and signed as instructed
- Oxygen prescribed for 72 hours and not signed as instructed
(please explain _____)
- Oxygen stopped before the end of 3 days/nights (give reason)
Reason for not completing prescribed oxygen treatment _____
- Patient is on the control group (no trial oxygen prescribed)

Clinical data during the first week after trial inclusion:

Antibiotics prescribed after randomization	YES	NO
Thrombolysis performed	YES	NO
Sedatives or antipsychotic drugs prescribed after randomization	YES	NO
Highest temperature during week 1		

Other clinical trials:

Has the patient been enrolled in any other clinical trials? YES / NO

If yes, please specify give name of trial:

Record of oxygen saturation and treatment during the first 3 days

Please check compliance with treatment daily and make sure night staff is aware of the study and assessments if saturation or oxygen treatment has not been documented as instructed.

Oxygen saturation at 24:00 (midnight) night 1	
Night staff checked and signed that oxygen is in place at 24:00	YES / NO / CONTROL
Oxygen saturation at 6 am night 1	
Night staff checked and signed that oxygen is in place at 06:00	YES / NO / CONTROL
Oxygen saturation at 12:00 (lunchtime) day 2	
Oxygen saturation at 24:00 (midnight) night 2	
Night staff checked and signed that oxygen is in place at 24:00	YES / NO / CONTROL
Oxygen saturation at 6 am night 2	
Night staff checked and signed that oxygen is in place at 06:00	YES / NO / CONTROL
Oxygen saturation at 12:00 (lunchtime) day 3	
Oxygen saturation at 24:00(midnight) night 3	
Night staff checked and signed that oxygen is in place at 24:00	YES / NO / CONTROL
Oxygen saturation at 6 am night 3	
Night staff checked and signed that oxygen is in place at 06:00	YES / NO / CONTROL
The highest oxygen saturation during the 3 days of trial treatment	
The lowest oxygen saturation during the 3 days of trial treatment	
The highest heart rate during the 3 days of trial treatment	
The highest systolic blood pressure during the 3 days of trial treatment	
The highest diastolic blood pressure during the 3 days of trial treatment	

CT /MRI diagnosis (please tick one of the boxes)

- Cerebral infarct
- Primary intracerebral haemorrhage
- Subdural haemorrhage
- Subarachnoid haemorrhage
- Brain tumour
- Head scan not performed
- Other (please specify) _____

Second CT head scan (if performed) date (dd-mm-yyyy)_____ New haemorrhage Yes / no

Final diagnosis (Please make a final diagnosis using the clinical presentation, time course, head scan. Tick only one of the boxes)

- Ischaemic stroke
- TIA
- Primary intracerebral haemorrhage
- Cerebrovascular accident without CT confirmation of aetiology
- Other (Please specify) _____

Is the patient still in hospital at day 7? YES/ NO

If no, give date of discharge (DD-MM-YYYY)

NIH Stroke Scale

1a Level of Consciousness (LOC)	0	Alert – <i>keenly responsive</i>	
	1	Drowsy – <i>arousable by minor stimulation to obey, answer, or respond</i>	
	2	Stuporous – <i>requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped)</i>	
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Total			

TOAST criteria (complete for infarcts only)

- Large-artery atherosclerosis (LAA)**
(tick this if there is Imaging evidence of >50% stenosis of intracranial or extracranial artery)
- Cardioembolism (CE)**
(Evidence of a medium-risk cardiac source of embolism **and** no other cause of stroke)
- Small-artery occlusion (lacunar infarct)**
(Clinically lacunar syndrome **and** lacunar infarct on CT **and** no evidence for ipsilat. LAA or CE)
- Acute ischaemic stroke of other determined aetiology**
(rare causes of stroke, such as nonatherosclerotic vasculopathies, hypercoagulable states, or haematological disorders **and** no evidence for LAA or CE)
- Ischaemic stroke of undetermined aetiology**
(any patient who does not fit the above, e.g. fully investigated patients with >1 potential cause of stroke or patients who have not been fully investigated)

Large-artery atherosclerosis (LAA)

These patients will have clinical and brain imaging findings of either significant (>50%) stenosis or occlusion of a major brain artery or branch cortical artery, presumably due to atherosclerosis. Clinical findings include those of cerebral cortical impairment (aphasia, neglect, restricted motor involvement, etc.) or brain stem or cerebellar dysfunction. A history of intermittent claudication, transient ischaemic attacks (TIAs) in the same vascular territory, a carotid bruit, or diminished pulses helps support the clinical diagnosis. Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5cm in diameter on CT or MRI are considered to be of potential large-artery atherosclerotic origin. Supportive evidence by duplex imaging or arteriography of a stenosis of greater than 50% of an appropriate intracranial or extracranial artery is needed. Diagnostic studies should exclude potential sources of cardiogenic embolism. The diagnosis of stroke secondary to large-artery atherosclerosis cannot be made if duplex or arteriographic studies are normal or show only minimal changes.

Cardioembolism (CE)

This category includes patients with arterial occlusions presumably due to an embolus arising in the heart. Cardiac sources are divided into high-risk and medium-risk groups based on the evidence of their relative propensities for embolism. At least one cardiac source for an embolus must be identified for a possible or probable diagnosis of cardioembolism stroke. Clinical and brain imaging finding are similar to those described for large-artery atherosclerosis. Evidence of a previous TIA or stroke in more than one vascular territory or systemic embolism supports a clinical diagnosis of cardiogenic stroke. Potential large-artery atherosclerotic sources of thrombosis or embolism should be eliminated. A stroke in a patient with a medium-risk cardiac source of embolism and no other cause of stroke is classified as a possible cardioembolic stroke.

Small-artery occlusion (lacunar infarct)

This category includes patients whose strokes are often labelled as lacunar infarcts in other classifications. The patient should have one of the traditional clinical lacunar syndromes and should not have evidence of cerebral cortical dysfunction. A history of diabetes mellitus or hypertension supports the clinical diagnosis. The patient should also have a normal CT/MRI or examination or a relevant brain stem or subcortical hemispheric lesion with a diameter of less than 1.5 cm demonstrated. Potential cardiac sources for embolism should be absent and evaluation of the large extracranial arteries should not demonstrate a stenosis of greater than 50% in an ipsilateral artery.

Acute ischaemic stroke of other determined etiology

This category includes patients with rare causes of stroke, such as nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders. Patients in this group should have clinical and CT or MRI findings of an acute ischaemic stroke, regardless of the size or location. Diagnostic studies such as blood tests or arteriography should reveal one of those unusual causes of stroke. Cardiac sources of embolism and large-artery atherosclerosis should be excluded by other studies.

Ischaemic stroke of undetermined aetiology

In several instances, the cause of a stroke cannot be determined with any degree of confidence. Some patients will have no likely aetiology determined despite an extensive evaluation. In others, no cause is found but the evaluation was cursory. This category also includes patients with two or more potential causes of stroke so that the physician is unable to make a final diagnosis. For example, a patient with a medium-risk cardiac source of embolism who also has another possible cause of stroke identified would be classified as having a stroke of undetermined aetiology. Other examples would be a patient who has atrial fibrillation and an ipsilateral stenosis of 50%, or the patient with a traditional lacunar syndrome and an ipsilateral carotid stenosis of 50%.

Completed by : Print Name _____ Sign and Date

Stroke Oxygen Study

Week 1 (Contact form)

For patients who were incompetent to sign consent at recruitment:

Competent to sign today? Yes No

If yes, explain study again and ask patient to sign patient confirmation of consent (after recovery) form.

Preferred contact address and telephone number for the follow-up questionnaires:

Name:

Street and Number:

Town, County, country:

Postcode:

Tel No:

Mobile no:

Alternative contact address and tel number if preferred address cannot be contacted:

Name:

Street and Number:

Town, County, country:

Postcode:

Tel No:

Mobile no:

Address and telephone number of the patient's general practitioner:

Name of GP:

Street and Number:

Town, County, country:

Postcode:

Tel No:

Fax:

Alternative follow-up arrangements if the patient is unable to complete the 3, 6 or 12 month questionnaire or prefers a personal appointment:

Clinic Appointment

Other

**Please complete on line or fax the week 1 assessment form the week 1 contact form and the
NIHSS score sheet for randomisation and week 1 to (0300 123 0894)**

Completed by : Print Name _____ Sign and Date

Stroke Oxygen Study

Notification of Death (Assessment Form 3)

Name

Randomisation number:

Date of Death

Has the cause of death been confirmed by autopsy?

Yes

No

Likely cause of death (tick one box only)

Neurological damage due to the initial stroke

Recurrent stroke

Pneumonia

Other infection

Pulmonary Embolism

Ischaemic heart disease

Other cause of death (please specify) _____

Completed by : Print Name _____ Sign and Date

Stroke Oxygen Study

Serious Adverse Event Notification (Assessment Form 4)

Please complete form below and fax to 0300 123 0894 and 01782 441624 ASAP within 24 hours of becoming aware of the event.

Trial name: The Stroke Oxygen Study

ISRCTN52416964

Report date and time (dd-mm-yyyy hh:mm) _____

Date of Enrolment _____

Centre name _____

Country _____

Randomisation number _____ Date _____ Age (years) _____ Sex: Male/female

Suspect treatment. tick the treatment you suspect as the cause of the adverse reaction:

- Oxygen 2L/min / 3L/min (please delete) inhaled via nasal cannulae
 Oxygen 2L/min / 3L/min (please delete) for 3 nights inhaled via nasal cannulae
 Control (room air)

Event information

When did this event happen with regard to the treatment phase?	Before / During / After
Is it a Serious adverse event?	
An adverse event is defined as serious if any of A-F has been answered with yes. Please describe the event regardless of your answer to A-F. If the answer to questions A-F is 'no' in every case this is not a serious event - Please complete form (R & D-RF-SOS-001)	
A. Did the event result in death?	Yes / No
B. Is / was the event life threatening?	Yes / No
C. Did / does the event lead to hospitalization or prolonged hospitalization?	Yes / No
D. Did / does the event result in persistent or significant disability / incapacity?	Yes / No
E. Did / does the event result in congenital anomaly / birth defect / carcinogenesis?	Yes / No
F. Does the investigator consider the event a serious adverse event for other reasons	Yes / No

A1 Date and time the Adverse Event began (dd-mm-yyyy hh:mm)	
Nature of event	Single / Multiple Episodes
Intensity of event / Grading of Serious Adverse Event	Mild / Moderate / Severe
A2 Relationship to study drug(s) / Attribution of Serious Adverse Event	Definitely not/Unrelated Unlikely / Possibly / Probably / Definitely / Unknown
A3 Action taken regarding study drug(s)	None Dose(s) missed Discontinued
A4 Clinical outcome	Recovered Not Yet Recovered Died

B. Please describe the event in detail, providing any relevant medical information. i.e. pathology, radiology, ECG, bacteriology, biochemistry or clinical reports / information.

AE / SAE Event Categories v1.0

To be used with SAE form v1 amendment 2 (30. Aug.1009)

Cardiovascular

Acute coronary syndrome (ACS)
Atrial fibrillation (AF)
Bradycardia
Cardiac failure
Cardiac dysrhythmia
Chest pain
Collapse
Deep vein thrombosis (DVT)
Hypertension
Hypotension
Myocardial infarction (MI)
Pulmonary embolism (PE)
Tachycardia
Unstable angina

Central nervous system

Agitation
Anxiety
Cerebral oedema
Complication of initial stroke
Dementia
Depression
Dysphagia
Extension of initial stroke
Haemorrhagic transformation (of infarct, HTI)
Headache
Intracerebral bleed
Intracranial/extracerebral bleed
Recurrent stroke
Sedation
Seizure
Sensory loss
Transient ischaemic attack (TIA)
Vertigo
Visual loss
Weakness

Cutaneous

Flushing
Hypersensitivity inc. oropharangeal swelling, urticaria
Rash

Gastro-intestinal

Abdominal pain
Constipation
Diarrhoea
Dysphagia
Gastrointestinal bleed
Gastrointestinal disturbance
Incontinence, faecal
Heartburn
Hepatitis
Nausea
Oral ulceration
Pancreatitis
Vomiting
Weight loss

Genito-urinary

Sexual dysfunction
Incontinence, urinary
Renal impairment
Urinary retention
Urinary tract infection (UTI)

Haematological

Anaemia
Leukopenia
Methaemoglobinaemia
Thrombocytopenia

Immunological

Anaphalactoid reaction
Hypersensitivity

Miscellaneous

Acid base disturbance
Bacteraemia
Death unattended
Diaphoresis
Hyponatraemia
Hypernatraemia
Acidosis
Extracranial bleeding (not GI haemorrhage)
Fall
Fatigue
Hyperglycaemia
Hyperuricaemia
Infection (not otherwise specified)
Malignancy
Muscle twitching
Vascular event (not otherwise specified)

Respiratory

Asthma
Bronchospasm
Chest infection
Hypoxia
Pneumonia
Pulmonary embolism (PE)
Shortness of breath

Oxygen-related

Respiratory depression
Drying of mucous membranes

Other (specify)
