| **Identification sticker** or<br>Name<br>Sex male / female<br>DOB DD MON YYYY<br>Unit No /Hiss No | **Stroke Oxygen Study**<br>**Randomisation Form**<br>Trial Centre name<br>Investigator name |
|---|---|

**STEP 1 ELIGIBILITY FOR TRIAL INCLUSION**

| | | |
|---|---|---|
| Time since admission with a clinical diagnosis of stroke (WHO criteria) less than 24h | YES | NO |
| Time since stroke onset less 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 are in the shaded boxes.

**STEP 2 PATIENT DETAILS**

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

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 – *keenly responsive* |
| | 1 | Drowsy – *arousable by minor stimulation to obey, answer, or respond* |
| | 2 | Stuporous – *requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped*) |
| | 3 | **Comatose** – *responds only with reflex motor or autonomic effects or totally unresponsive, flaccid* |
| **1b LOC Questions** | 0 | Answers both correctly |
| | 1 | Answers one correctly |
| | 2 | Both incorrect **or no reply** |
| | | Patient is asked to state the month & his/her age |
| **1c LOC Commands** | 0 | Obeys both correctly |
| | 1 | Obeys one correctly |
| | 2 | Both incorrect **or no reply** |
| | | Patient is asked to open & close eyes, grip & release normal hand |
| **2. Best Gaze** | 0 | Normal |
| | 1 | Partial gaze palsy – *gaze is abnormal in one or both eyes, no forced deviation/total gaze paresis* |
| | 2 | Forced deviation – *or total gaze paresis not overcome by oculocephalic maneouvre* |
| **3. Visual Fields** | 0 | No visual loss (**or in coma**) |
| | 1 | Partial hemianopia |
| | 2 | Complete hemianopia |
| | 3 | Bilateral Hemianopia – *including cortical blindness* |
| **4. Facial Palsy** | 0 | Normal |
| | 1 | Minor - *flattened nasolabial fold, asymmetry on smiling* |
| | 2 | Partial – *total or near total paralysis of lower face* |
| | 3 | Complete - *absent facial movement in upper and lower face on one or both sides* |

| **5/6 Best Motor ARM** | Right | Left | |
|---|---|---|---|
| | 0 | 0 | No drift – *holds limb at 90 degrees for full 10 seconds* |
| | 1 | 1 | Drift - *drifts down but does not hit bed* |
| | 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 – *holds limb at 45 degrees for full 5 seconds* |
| | 1 | 1 | Drift - *drifts down but does not hit bed* |
| | 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 – *patient feels pinprick is less sharp or is dull on affected side* |
| | 2 | Dense loss (**or in coma)** - *patient is unaware of being touched on face, arm, leg* |
| **11. Best Language** | 0 | No dysphasia |
| | 1 | Mild – moderate dysphasia *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.* |
| | 2 | Severe dysphasia - *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* |
| | 3 | Mute *no usable speech or auditory comprehension,* **or in coma**. |
| **12. Dysarthria** | 0 | Normal articulation |
| | 1 | Mild – moderate dysarthria - *patient slurs some words, can be understood with some difficulty.* |
| | 2 | Unintelligible or worse - *speech is so slurred as to be unintelligible (absence of or out of proportion to dysphasia) or is mute/anarthric,* **or in coma** |
| **13. Neglect** | 0 | No neglect **(or in coma)** |
| | 1 | Partial neglect - *Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities* |
| | 2 | Complete neglect - *Profound hemi-inattention or hemi-inattention to more than one modality. Does not recognise own hand or orients to only one side of space* |
| **Total:** | | |

**STEP 5 CONTACT likely or preferred location for week 1 follow-up**

☐Clinic
☐Home
☐Hospital same as randomizing centre
☐Hospital different to randomizing centre – please give name
☐Other _____

**STEP 6 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 7 RANDOMISATION** via http://www.so2s.co.uk or [redacted] (day) or [redacted] (after hours)

Date and time of randomisation ☐ dd-mon-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.

# 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 MON 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 randomizaton | 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.

| | |
|---|---|
| Day 1 | |
| Oxygen saturation at 24:00 (midnight) night 1 | |
| Oxygen is in place at 24:00 | YES / NO |
| Oxygen saturation at 6 am night 1 | |
| Oxygen is in place at 06:00 | YES / NO |
| Day 2 | |
| Oxygen saturation at 12:00 (lunchtime) day 2 | |
| Oxygen saturation at 24:00 (midnight) night 2 | |
| Oxygen is in place at 24:00 | YES / NO |
| Oxygen saturation at 6 am night 2 | |
| Oxygen is in place at 06:00 | YES / NO |
| Day 3 | |
| Oxygen saturation at 12:00 (lunchtime) day 3 | |
| Oxygen saturation at 24:00(midnight) night 3 | |
| Oxygen is in place at 24:00 | YES / NO |
| Oxygen saturation at 6 am night 3 | |
| Oxygen is in place at 06:00 | YES / NO |

| | |
|---|---|
| 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-mon-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) _____

**Date of discharge** …….. (DD-MON-YYYY)

*If this is not available at the day 7 follow-up please complete once patient has been discharged.*

**Discharge location (***If this is not available at the day 7 follow-up please complete once patient has been discharged):*

☐ Patients own home
☐ Home of a relative
☐ Residential home
☐ Nursing home
☐ Another hospital – please provide name ……..
☐ Other ……..

**Pre-Stroke Rankin**

*This is to be completed by the researcher with the either the patient, a relative or carer in relation to how the patient was before the stroke (i.e. based on the day before the stroke).*

☐ No symptoms at all
☐ Few symptoms, but able to carry out usual activities as normal
☐ Unable to carry out all usual activates, but can look after own affairs without assistance
☐ Need some help with looking after own affairs, but can walk without assistance
☐ Unable to walk or attend bodily needs without assistance, but constant care not needed
☐ Major symptoms that severely handicap. Bedridden, incontinent and require constant attention day and night

Completed by:

☐ Patient
☐ Other, please specify _____

Pre-stroke EQ – 5D

*This is to be completed by the researcher with the either the patient, a relative or carer in relation to how the patient was before the stroke (i.e. based on the day before the stroke).*

**Mobility -** Please tick the box which best describes the patients level of mobility before the stroke

☐ I had no problems walking
☐ I had some problems walking
☐ I was confined to bed

**Self care -** Please tick the box which best describes the patients ability to care for themselves before the stroke

☐ I had no problems with self care
☐ I had some problems washing and dressing
☐ I was unable to wash or dress myself

**Usual activities** - Please tick one box next to the statement which best describes their ability to perform their usual activities before the stroke

☐ I was able to perform my usual activities
☐ I has some problems performing my usual activities
☐ I was unable to perform my usual activities

**Pain or discomfort** - Please tick one box next to the statement which best describes their level of pain or discomfort before the stroke

☐ I had no pain or discomfort
☐ I had moderate pain or discomfort
☐ I had extreme pain or discomfort

**Anxiety and depression -** Please tick one box next to the statement which best describes their level of anxiety and depression before the stroke

☐ I was not anxious or depressed
☐ I was moderately anxious or depressed
☐ I was extremely anxious or depressed

Completed by:

☐ Patient

☐ Other, please specify _____

## NIH Stroke Scale

| | | |
|---|---|---|
| **1a Level of Consciousness (LOC)** | 0 | Alert – *keenly responsive* |
| | 1 | Drowsy – *arousable by minor stimulation to obey, answer, or respond* |
| | 2 | Stuporous – *requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped*) |
| | 3 | **Comatose** – *responds only with reflex motor or autonomic effects or totally unresponsive, flaccid* |
| **1b LOC Questions** | 0 | Answers both correctly |
| | 1 | Answers one correctly |
| | 2 | Both incorrect **or no reply** |
| | | Patient is asked to state the month & his/her age |
| **1c LOC Commands** | 0 | Obeys both correctly |
| | 1 | Obeys one correctly |
| | 2 | Both incorrect **or no relpy** |
| | | Patient is asked to open & close eyes, grip & release normal hand |
| **2. Best Gaze** | 0 | Normal |
| | 1 | Partial gaze palsy – *gaze is abnormal in one or both eyes, no forced deviation/total gaze paresis* |
| | 2 | Forced deviation – *or total gaze paresis not overcome by oculocephalic maneouvre* |
| **3. Visual Fields** | 0 | No visual loss **(or in coma)** |
| | 1 | Partial hemianopia |
| | 2 | Complete hemianopia |
| | 3 | Bilateral Hemianopia – *including cortical blindness* |
| **4. Facial Palsy** | 0 | Normal |
| | 1 | Minor - *flattened nasolabial fold, asymmetry on smiling* |
| | 2 | Partial – *total or near total paralysis of lower face* |
| | 3 | Complete - *absent facial movement in upper and lower face on one or both sides* |

| **5/6 Best Motor ARM** | Right | Left | |
|---|---|---|---|
| | 0 | 0 | No drift – *holds limb at 90 degrees for full 10 seconds* |
| | 1 | 1 | Drift - *drifts down but does not hit bed* |
| | 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 – *holds limb at 45 degrees for full 5 seconds* |
| | 1 | 1 | Drift - *drifts down but does not hit bed* |
| | 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 – *patient feels pinprick is less sharp or is dull on affected side* |
| | 2 | Dense loss **(or in coma)** - *patient is unaware of being touched on face, arm, leg* |
| **11.Best Language** | 0 | No dysphasia |
| | 1 | Mild – moderate dysphasia *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.* |
| | 2 | Severe dysphasia - *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* |
| | 3 | Mute *no usable speech or auditory comprehension,* **or in coma**. |
| **12. Dysarthria** | 0 | Normal articulation |
| | 1 | Mild – moderate dysarthria - *patient slurs some words, can be understood with some difficulty*. |
| | 2 | Unintelligible or worse - *speech is so slurred as to be unintelligible (absence of or out of proportion to dysphasia) or is mute/anarthric,* **or in coma** |
| **13. Neglect** | 0 | No neglect **(or in coma)** |
| | 1 | Partial neglect - *Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities* |
| | 2 | Complete neglect - *Profound hemi-inattention or hemi-inattention to more than one modality. Does not recognise own hand or orients to only one side of space* |
| **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 arteriographay 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** [redacted]

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 [redacted] and [redacted]
ASAP within 24 hours of becoming aware of the event.

Trial name: The Stroke Oxygen Study
**ISRCTN52416964**

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

_____

Date of Enrolment _____Adverse Event date and time (dd-mon-yyyy hh:mm)

_____

Centre name

_____Country_____

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

**Event information**

| | |
|---|---|
| When did this event happen with regard to the treatment phase? | Before / During / After |
| **Is it a Serious adverse event?**<br><br>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** Nature of event | Single<br>Multiple Episodes | |
| Intensity of event / Grading of Serious Adverse Event | Mild<br>Moderate<br>Severe | |
| **A2** Relationship to study drug(s) / Attribution of Serious Adverse Event | Definitely not<br>Unrelated<br>Unlikely | Possibly<br>Probably<br>Definitely<br>Unknown |
| **A3** Action taken regarding study drug(s) | None | Dose(s) missed<br>Discontinued |
| **A4** Clinical outcome | Recovered | Not Yet Recovered<br>Died |

**B**. Please describe the event in detail, providing any relevant medical information. i.e. pathology, radiology, ECG, bacteriology, biochemistry or clinical reports / information.
If the patient has been re-admitted to hospital please provide re-admission date, discharge date and length of stay (days)

| **C. Assessment of event by local Investigator** | |
|---|---|
| C1. SAE category as adjudicated by local investigator<br>(see attached SAE event categories for guidance) | |
| C2. Do you consider this SAE unexpected i.e. a Suspected Unexpected Serious Adverse Reaction (SUSAR)? | Yes / No |
| Form submission sign off - Enter your NAME: | |
| Date SAE Reported | |
| Time (24 hour clock) SAE Reported | |
| Have you checked that all entries above are correct? | Yes / No |

| **D. Assessment by the Chief Investigator** | |
|---|---|
| Is this event considered an SAE by the Chief investigator or deputy? | Yes / No |
| Is this event considered to be a SUSAR by the Chief investigator /deputy? | Yes / No |
| If the answer to SUSAR is yes, do you want to send the report to MHRA/ COREC now | |
| Confirmation of date (dd-mm-yyyy) sent to MHRA/COREC | |
| Confirmation of time [24 hour clock] sent to MHRA/COREC | |
| Signature of Chief investigator: | |
| Follow-up report required | Yes / No |
| Notes | |

## 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)**
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