SAE adjudication

Record ID _____

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

UK ISRCTN 98886991
UK IRAS306761
UK CPMS 50913
WHO UTN U1111-1273-9942

SAE adjudication form v1.4

SAE Form for all SAEs to end day 9, and fatal SAEs from day 10 onwards. This form may also be used for device or procedure related SAEs (SADEs) which are collected days 0-14.

▶ Please check SAE number.

Section A: Participant details

A1 Centre name [record-dag-label]
A2 Participant ID [record-name]
A3 Participant initials [initials]

Section B: More details

B1. Sex

[sex]

B2. Age at randomisation

[age]

B3. Time from onset to randomisation

[days_stroke_randomisation]

B4a. mRS (premorbid)

[mrs_premorbid]

B4b. mRS (at time of enrolment)

[mrs_000]

B5. Stroke type

[stroke_type]

B6. Stroke location

[stroke_location]

B7. Stroke syndrome

[stroke_syndrome]

B8. Weight (or estimated weight)

[weight_000] kg

B9. Height (or estimated height)

[height_000] m

B10. Body mass index (BMI)

[bmi_000]
BMI = Weight / height²

B11. Admission scan diagnosis?

[scan_diagnosis_admission]

B12. NIHSS score

[nihss_total_000]

B13. GCS total

[gcs_total_000]

Section C: SAE details

C1. Date of SAE report

[date_sae_report][current-instance]
(dd-mm-yyy)

C1a. Number of days from admission to SAE report date

[day_admit_reported_sae][current-instance]

C2. Date of onset of event:

[date_sae_onset][current-instance]
(dd-mm-yyyy)

C3. Time of onset of event:
Enter 00:00 if unknown

[time_sae_onset][current-instance]

C3a. Number of days from admission to onset

[day_admit_onset_sae][current-instance]

C4. Date deemed serious:

[date_sae_serious][current-instance]
(dd-mm-yyy)

C5. Time deemed serious:
Enter 00:00 if unknown

[time_sae_serious][current-instance]

C6. Event description and name

[sae_description][current-instance]

C7a. Event diagnosis/category/type

[sae_diagnosis][current-instance]

C7b. If 'other'

[sae_diagnosis_other][current-instance]

C8. Serious criteria

☑ Fatal

☑ Life Threatening

☑ Hospitalisation or prolongation of hospitalisation

☑ Persistent or significant disability or incapacity

☑ A congenital anomaly or birth defect

☑ Medically important

☑ Not serious - only use this if probably or definitely related to device, i.e. an adverse device effect

C9. Specify why medically important?

[sae_serious_description][current-instance]

C10. Severity of event/effect?

[sae_severity][current-instance]

C11. Causality:
(detail all possible and suspected causes)

[sae_causality][current-instance]

Section D: Device related

D1a. Relationship to study device

{show_causality_desc_sae_adj}

[sae_relationship][current-instance]

Causality
Not related or improbable: a clinical event including laboratory test abnormality with temporal relationship to trial treatment administration which makes a causal relationship incompatible or for which other drugs, chemicals or disease provide a plausible explanation. This will be counted as "unrelated" for notification purposes.

Possible: a clinical event, including laboratory test abnormality, with temporal relationship to trial treatment administration which makes a causal relationship a reasonable possibility, but which could also be explained by other drugs, chemicals or concurrent disease. This will be counted as "related" for notification purposes.

Probable: a clinical event, including laboratory test abnormality, with temporal relationship to trial treatment administration which makes a causal relationship a reasonable possibility, and is unlikely to be due to other drugs, chemicals or concurrent disease. This will be counted as "related" for notification purposes.

Definite: a clinical event, including laboratory test abnormality, with temporal relationship to trial treatment administration which makes a causal relationship a reasonable possibility, and which can definitely not be attributed to other causes. This will be counted as "related" for notification purposes.

An AE whose causal relationship to the study intervention is assessed by the Chief Investigator as "possible", "probable", or "definite" is a trial intervention related SAE.

With regard to the criteria above, medical and scientific judgment shall be used in deciding whether prompt reporting is appropriate in that situation.

D1b. Anticipated device effect?

If the event was probably or definitely related to the device, is this an anticipated device effect?

YES

Section E: SAE, SADE, USADE Action taken

E1. Calculated type (SAE/ SAR/ USADE)

SAE (1)

E1. Calculated type (SAE/ SAR/ USADE)

SADE (2)

E1. Calculated type (SAE/ SAR/ USADE)

USADE (3)

E2. If the SAE occurred during the treatment phase, will treatment continue?

[sae_pes][current-instance]

E3a. Action taken: Treatment provided

[sae_action][current-instance]

E3b. Action taken: Detail Treatment and action taken and whether trial participation is to continue

[sae_action_describe][current-instance]

Outcome

E4a. Outcome

[sae_outcome][current-instance]

E4b. Date/time of: event resolved, event resolved with sequalea or participant died

[datetime_sae_end][current-instance]
(dd-mm-yyy)

E4c. Number of days from onset to resolution date

[day_onset_resolve_sae][current-instance]

Autopsy

E5a. Was an autopsy/post mortem performed?

[sae_autopsy][current-instance]

E5b. If an autopsy was performed, what was the cause of death?

[sae_autopsy_cause][current-instance]

Section F: Investigator information.

F1. Name of the person who collected the information

[assessor_name_sae][current-instance]

F2a. Professional role

[assessor_role_sae][current-instance]

F2b. If "Other"

[assessor_role_other_sae][current-instance]

F3. Role involves working on stroke wards

[assessor_site_sae][current-instance]

F4. Name of the person entering the information (if different)

[assessor_other_name_sae][current-instance]

Values are missing

[nil_comments_sae][current-instance]

Section G: Adjudicator assessment.

G1. Date of adjudication

_____
(Date DD-MM-YYYY)

G2a. SAE category as assessed by you

- ◯ Not an SAE
- ◯ Not relevant
- ◯ Other (please state medical condition)
- ◯ Acute coronary syndrome (ACS)
- ◯ Angina
- ◯ Angina - unstable (UA)
- ◯ Arterial thrombosis (any site)
- ◯ Atrial fibrillation (AF) or atrial flutter
- ◯ Atrioventricular Block
- ◯ Bradycardia
- ◯ Cardiac (mural) thrombus
- ◯ Cardiac dysrhythmia
- ◯ Cardiac failure or pulmonary oedema
- ◯ Carotid dissection
- ◯ Chest pain (NOT cardiac)
- ◯ Collapse
- ◯ Deep vein thrombosis (DVT)
- ◯ Endocarditis
- ◯ Hypertension
- ◯ Hypotension
- ◯ Left atrial myxoma
- ◯ Myocardial infarction (NSTEMI)
- ◯ Myocardial infarction (STEMI)
- ◯ Patent foramen ovale (PFO)
- ◯ Peripheral arterial disease
- ◯ Peripheral artery embolism
- ◯ Presyncope
- ◯ Pulmonary embolism (PE)
- ◯ QT prolongation
- ◯ Sudden cardiac death (SCD)
- ◯ Supraventricular tachycardia (SVT)
- ◯ Syncope
- ◯ Systemic embolism
- ◯ Tachycardia
- ◯ Torsade de pointes
- ◯ Vascular event (not otherwise specified)
- ◯ Vasovagal episode
- ◯ Venous thrombosis (any site)
- ◯ Agitation
- ◯ Akathisia
- ◯ Alzheimer's disease
- ◯ Anxiety - apprehension
- ◯ Brain tumour - primary
- ◯ Brain tumour - secondary
- ◯ Cerebral oedema
- ◯ Complication of initial stroke
- ◯ Cortical vein thrombosis
- ◯ Dementia
- ◯ Depression
- ◯ Disturbance in colour vision
- ◯ Dizziness
- ◯ Dystonia
- ◯ Expansion of intracerebral haemorrhage - with hydrocephalus
- ◯ Expansion of intracerebral haemorrhage - without hydrocephalus
- ◯ Extension of ischaemic stroke
- ◯ Extra dural bleed
- ◯ Haemorrhagic transformation (of infarct, HTI)
- ◯ Hallucinations
- ◯ Headache
- ◯ Hydrocephalus
- ◯ Intracerebral haemorrhage, including recurrence
- ◯ Intracranial aneurysm
- ◯ Intracranial/extracerebral bleed
- ◯ Intraventricular haemorrhage
- ◯ Ischaemic stroke, including recurrence
- ◯ Loss of consciousness
- ◯ Nerve entrapment

◯ Neuroleptic malignant syndrome
◯ Neurological deterioration
◯ Oculogyric crisis
◯ Parkinsonism
◯ Sedation
◯ Seizure / convulsions
◯ Sensory loss
◯ Stroke - undetermined / no imaging
◯ Sub-arachnoid haemorrhage
◯ Subdural haematoma
◯ Swelling of the original infarct
◯ Tardive dyskinesia
◯ Transient ischaemic attack (TIA)
◯ Vertigo
◯ Visual loss
◯ Weakness
◯ Acute type 1 respiratory failure
◯ Asthma
◯ Bronchitis
◯ Bronchospasm
◯ Chest infection
◯ Chronic obstructive pulmonary disease (COPD)
◯ COVID-19 / SARS-CoV-2 infection
◯ Emphysema
◯ Exacerbation of COPD
◯ Hypoxia
◯ Interstitial pneumonitis
◯ Pleural effusions
◯ Pneumonia
◯ Pneumothorax
◯ Primary lung cancer
◯ Pulmonary fibrosis
◯ Respiratory tract infection, lower (LRI/LRTI)
◯ Respiratory tract infection, upper (URI/URTI)
◯ Secondary lung cancer
◯ Shortness of breath
◯ Abdominal pain
◯ Bowel ischaemia
◯ Carcinoma bowel
◯ Cholecystitis
◯ Colitis
◯ Constipation
◯ Diarrhoea
◯ Diverticulitis
◯ Dysphagia
◯ Gall stones
◯ Gastroenteritis
◯ Gastrointestinal bleed
◯ Gastrointestinal disturbance
◯ Gastrointestinal infarction
◯ Haematemesis
◯ Heartburn
◯ Hepatitis
◯ Hernia
◯ Incontinence, faecal
◯ Liver/hepatic impairment/dysfunction
◯ Melaena
◯ Nausea
◯ Oesophagitis
◯ Oral ulceration
◯ Pancreatitis
◯ Peptic ulcer
◯ Perforated GI viscus
◯ PR bleed
◯ Primary liver carcinoma
◯ Secondary liver metastasis
◯ Stomatitis
◯ Vomiting
◯ Weight loss
◯ Acute Kidney Injury (AKI)
◯ Carcinoma bladder

◯ Glomerulonephritis
◯ Haematuria
◯ Incontinence, urinary
◯ Primary renal tumour
◯ Prostate cancer
◯ Renal cyst
◯ Renal impairment/failure
◯ Sexual dysfunction
◯ Urinary retention
◯ Urinary tract infection (UTI)
◯ Agranulocytosis/granulocytopenia
◯ Allergic reaction
◯ Amenorrhoea
◯ Anaemia
◯ Anaphylactic reaction
◯ Anaphylactic shock
◯ Angioedema
◯ Aplastic anaemia
◯ Eosinophilia
◯ Galacotrrhoea
◯ Gynaecomastia
◯ Hyperprolcatinaemia
◯ Hypersensitivity
◯ Hypersensitivity inc. oropharangeal swelling, urticaria, angiodema
◯ Leukopenia
◯ Lymphadenopathy
◯ Methaemoglobinaemia
◯ Neutropaenia
◯ Pancytopenia
◯ Polycythaemia
◯ Sulfhaemoglobinaemia
◯ Thrombocytopenia
◯ Thrombotic thrombocytopenic purpura (TTP)
◯ Urticaria
◯ Vasculitis
◯ Acid base disturbance
◯ Dehydration
◯ Diabetes
◯ Diaphoresis
◯ Electrolyte disturbance
◯ Hyperglycaemia
◯ Hyperuricaemia
◯ Hypoglycaemia
◯ Arthralgia
◯ Arthritis (not specified)
◯ Bullous dermatitis
◯ Burning sensation of skin
◯ Cellulitis
◯ Contact dermatitis
◯ Cramps
◯ Eczema
◯ Erythema of skin
◯ Fall
◯ Flushing
◯ Fracture / fractured bone
◯ Gout
◯ Infected skin ulcer
◯ Irritation of skin
◯ Muscle twitching
◯ Myalgia
◯ Myositis
◯ Osteoarthritis
◯ Petechia / petechiae
◯ Pressure ulcer
◯ Pruritus
◯ Rash
◯ Rheumatoid arthritis
◯ Acute alcohol intoxication
◯ Asthenia
◯ Bacteraemia - septicaemia

	◯ Confusion ◯ Death due to frailty / old age ◯ Death unattended ◯ Drug error ◯ Extracranial bleeding (not GI haemorrhage) ◯ Fatigue - malaise ◯ Fever ◯ Infection (not otherwise specified) ◯ Malignancy/cancer ◯ MRSA infection ◯ Musculoskeletal pains ◯ Phlebitis ◯ Septic shock ◯ Septicaemia ◯ Suicide ◯ Tumour - benign ◯ Tumour - malignant ◯ Unknown (Select Unknown from list if unknown)
G3b. If 'other', please state the medical condition (diagnosis, not treatment)	_____
G4. Certainty of event diagnosis	◯ Possible ◯ Probable ◯ Definite
G5. Relationship to study device	◯ Not related ◯ Unlikely ◯ Possibly ◯ Probably ◯ Definitely (Choose one answer)
G6a. Please classify the event	◯ SAE ◯ SADE ◯ USADE
G6b. For a USADE, please check box to confirm	☐ For a USADE, please check box to confirm
G7. Comments An email will only be sent to the trial office if "more information required" is selected below	_____
G8. Status of this assessment If more information is required, please enter comments above	◯ More information required from trial office ◯ Reviewing or resolved
G9. Name of the adjucator	_____

Comments and full explanation for missing data

Are any values missing due to tests not done (or measures not taken), or because data are unknown and every effort has been made to find the data - i.e. 'Not done' / 'Not known'?

◯ Yes
◯ No

If any values are missing, please provide a full explanation □□ Comments