SAE

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 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 consent form obtained.

Section A: Participant details

A1. Centre name :

A2. Participant ID :

A3. Participant initials :

Section B: PES Treatments

B1. PES treatments given

Section C: SAE details

C1. Date of report

Admission date: [date_admission] _____ (Date DD-MM-YYYY)

C1a. Number of days from admission to SAE report date

_____ (days from admission to reported SAE date)

C2. Date of onset of event:

_____ (Date DD-MM-YYYY)

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

_____
(time (hours:minutes))

C3a. Number of days from admission to onset

_____
(days from admission to onset)

C4. Date deemed serious:

_____
(Date DD-MM-YYYY)

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

_____
(Time (hours:minutes))

C6. Event description and name.

Please list any other devices (name, type) or drugs (name, dose, when started) that might be relevant.

_____
(Free text)

C7a. Event diagnosis/category/type.

Please select the sub-categories of the event.

Select Unknown from list if unknown

- ◯ 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
(Choose one answer)

C7b. If 'other', please state the medical condition (diagnosis, not treatment)

_____

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
(Choose one answer)

C9. Specify why medically important?

_____
(Free text)

C10. Severity of event/effect?

◯ Mild
◯ Moderate
◯ Severe
(Choose one answer)

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

_____
(Free text)

Section D: Device related

D1a. Relationship to study device

_____

◯ Not related
◯ Unlikely
◯ Possibly
◯ Probably
◯ Definitely
(Choose one answer)

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. Is this an anticipated device effect?

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

◯ Yes ◯ No
(Choose one answer)

D1c. Please confirm that the Device deficiency form has been completed or will be done next.

If the event was probably or definitely related to the device, please complete a device deficiency form.

◯ Yes ◯ No
(Choose one button)

Section E: SAE, SADE, USADE Action taken

E1. Calculate SAE=1, SADE=2, USADE=3

_____

_____
(Calculated)

ADVERSE EVENTS Definitions

Adverse event
This is any unfavourable and unintended sign, symptom, syndrome or illness that develops or worsens during the period of observation in the study.
An AE does include a / an:
1. exacerbation of a pre-existing illness.
2. increase in frequency or intensity of a pre-existing episodic event or condition.
3. condition detected or diagnosed after medicinal product administration even though it may have been present prior to the start of the study.
4. continuous persistent disease or symptoms present at baseline that worsen following the start of the study.

Serious Adverse Event (SAE)
This is any adverse event occurring following study mandated procedures, having received the study intervention or control that results in any of the following outcomes:
1. Death
2. A life-threatening adverse event
3. Inpatient hospitalisation or prolongation of existing hospitalisation
4. A disability / incapacity
5. A congenital anomaly in the offspring of a participant

Important medical events
These, that may not result in death, be life-threatening, or require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardise the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed here.

All adverse events will be assessed for seriousness, expectedness and causality:

A distinction is drawn between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined using the criteria above. Hence, a severe AE need not necessarily be serious.

Anticipated (serious) adverse events
These are associated with PES and so are only relevant to the active treatment group; they include, but are not limited to, the following:
• Sensation of stimulation at back of throat

Anticipated (serious) adverse events
These are associated with usual treatment other than PES, e.g., naso-gastric tube insertion, and so are relevant to both active and control treatment groups; they include, but are not limited to, the following:
• Bruising, skin
• Bleed, skin
• Chest infection
• Death
• Dyspnoea/shortness of breath
• Epistaxis
• Erosion, skin or mucosa
• Esophagitis, reflux
• Facial reflex, gagging
• Gastroesophageal reflux
• Gastrointestinal bleed
• Ileus
• Infection or irritation, tube insertion site or nasopharynx
• Ischaemia, intestinal
• Nausea
• Necrosis, skin or mucosa
• Peritonitis
• Pneumonia
• Pneumothorax
• Sepsis
• Sinusitis
• Sore throat
• Ulceration, skin or mucosa
• Vomiting

Anticipated (serious) adverse events, (S)AEs
These are associated with the index stroke or underlying co-morbid conditions associated with stroke, are also to be expected. These may include, but are not limited to, the following:

- Agitation
- Anaemia
- Angina/myocardial infarction/cardiac ischaemia
- Anxiety
- Atrial fibrillation/flutter
- Bradycardia
- Cardiac arrest
- Cardiac dysrhythmia
- Cellulitis
- Cerebral oedema
- Cerebral herniation
- Cerebral infarct extension/recurrence
- Coma/diminished level of consciousness
- Confusion
- Congestive heart failure/heart failure
- Constipation
- Death
- Deep venous thrombosis
- Dehydration
- Diarrhoea
- Dizziness/vertigo
- Dyspepsia
- Dysphagia
- Dyspnoea
- Extracranial bleeding
- Fever
- Gastritis or gastric/duodenal ulcer
- Gastrointestinal bleed
- Headache/migraine
- Haemorrhagic transformation of cerebral infarct
- Hydrocephalus
- Hypokalaemia
- Hyperglycaemia/hypoglycaemia
- Hypoxia
- Insomnia
- Intracerebral haemorrhage expansion
- Intraventricular haemorrhage
- Joint pain (arthralgia)
- Musculoskeletal pain
- Nausea
- Neurologic worsening
- Peripheral vascular disorder
- Peripheral oedema
- Pneumonia
- Pressure sore
- Pulmonary oedema
- Pulmonary embolism
- Seizure
- Sepsis
- Sleep apnoea
- Skin rash
- Limb spasticity
- Transient ischemic attack
- Urinary incontinence
- Urinary tract infection
- Vomiting

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

◯ Not relevant (event occurred before first PES treatment or after last PES treatment) or in control group
◯ PES will not continue
◯ PES will continue
(Choose one button)

E3a. Action taken: Treatment provided

◯ None
◯ Medication (new or change to existing prescription)
◯ New hospitalisation
◯ Intervention
◯ Other
(Choose one answer)

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

_____
(Free text)

Outcome

E4a. Outcome

◯ Resolved
◯ Event ongoing
◯ Recovered with sequalae
◯ Death
(Choose one answer)

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

_____
(Date time DD-MM-YYYY HH:MM)

E4c. Number of days from onset to resolution date

_____
(days from onset to end)

Autopsy

E5a. Was an autopsy/post mortem performed?

◯ Yes ◯ No
(Choose one answer)

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

_____
(Freetext)

Section F: Assessor information.

F1. Please enter the name of the person who collected the information

_____

F2a. What is his/her professional role?

◯ Doctor
◯ Research coordinator
◯ Nurse, clinical
◯ Research nurse
◯ Physiotherapist
◯ Occupation therapist
◯ Speech & Language therapist
◯ Other
(Choose one answer)

F2b. If "Other", please specify his/her role

_____

F3. Does his/her role involve working on stroke wards?

◯ Yes ◯ No
(Choose one answer)

F4. Please enter your name if you did not collect the information

_____

F5. Please sign the form

_____
(✍ Signature)

Section G: PI review.

G1. Reviwed by PI

◯ Reviewed
◯ Awaiting review

G2. I have reviewed and agree with this SAE

◯ Agreed
◯ Disagree
◯ Outstanding information

G3. Please enter PI name

_____

G4. Please sign the form

_____
(✍ Signature)

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