Eligibility

Record ID _____

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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

Eligibility form v1.5

▶ Please check consent form obtained.

Section A: Participant identifiers

A1. Centre name:

_____
(Centre)

A2. Participant ID :

_____
(Participant ID - REDCap auto generated)

A3. Participant initials (e.g. ABC or A-C)

_____
(3 uppercase letters, or 2 separated by a hyphen (-))

Section B: Inclusion/exclusion criteria Inclusion criteria (B1-B4 must be YES).

B. Start time

_____

B1. Adults (18 years and over)?

(Must be Yes to be eligible)

◯ Yes ◯ No
(Choose one answer)

B2. Recent IS or ICH stroke between 2 and 31 days previously?

(IS) Ischaemic or (ICH) haemorrhagic anterior or posterior circulation stroke (as diagnosed clinico-radiologically) at a stroke centre.

(Must be Yes to be eligible)

◯ Yes ◯ No
(Choose one answer)

B3. Clinical dysphagia defined as a functional oral intake scale (FOIS) score of 1 or 2 or 3?

FOIS 1: Nothing by mouth, feeding by NGT/PEG/RIG
FOIS 2: Tube dependent with minimal attempts of food or liquids
FOIS 3: Tube dependent with consistent oral intake of food or liquid

(Must be Yes to be eligible)

◯ Yes ◯ No
(Choose one answer)

B4. Baseline DSRS supervision score of either 3 (requiring therapeutic feeding by SALT team; on oral trials) or 4 (No oral feeding)

(Must be Yes to be eligible)

◯ Yes ◯ No

Exclusion criteria (B5-B21 must be NO).

B5. Non-stroke dysphagia?

e.g. due to traumatic brain haemorrhage, subarachnoid haemorrhage, brain tumour, Parkinson's disease, multiple sclerosis, severe dementia, head or neck cancer

(Must be No to be eligible)

◯ Yes ◯ No
(Choose one answer)

B6. Pre-stroke dysphagia?

(Must be No to be eligible)

◯ Yes ◯ No
(Choose one answer)

B7. Pre-stroke dependency?

(modified Rankin Scale, mRS 4/5)

(Must be No to be eligible)

◯ Yes ◯ No
(Choose one answer)

B8. NIHSS-1a. Conscious or obtunded on NIHSS stroke scale question 1A.

NIHSS-1a. Level of Consciousness

Score 0-1-2: Must be alert (score 0), arouse to minor stimulation (score 1) or require repeated stimulation (score 2) to be eligible.

Score 2-3: Patients with only movements to pain (also score 2) or postures/unresponsive (score 3) are ineligible.

Score 3: The investigator must choose a response if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation.

◯ 0 = Alert, keenly responsive
◯ 1 = Arouses to minor stimulation
◯ 2 = Requires repeated stimulation to arouse
◯ 2 = Movements to pain
◯ 3 = Postures or unresponsive
(⚠ To be eligible, NIHSS cannot be (2) Movements to pain or (3) Postures or unresponsive.)

B9. Ongoing or anticipated ventilation/intubation/tracheostomy? (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B10. Ongoing treatment of dysphagia with other forms of electrical/magnetic stimulation (e.g. NMES, TCDS, rTMS or Ampcare), or devices (e.g. EMST, IQORO, IOPI, biofeedback that uses EMG electrodes, or chin tuck against resistance using a ball/chin depressor) - this applies for the duration of the trial This was a protocol change in version 10.0 (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B11. Malignant middle cerebral artery syndrome? (although this typically presents before 4 days). (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B12. Pacemaker? PES should not be used in the presence of any active implanted electrical device, e.g., cochlear implant, implantable cardioverter-defibrillator (ICD), permanent pacemaker. (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B13. Need for >35% oxygen of oxygen/minute? (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B14. Two or more NGT tubes pulled out unless nasal bridle in place? (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B15. Investigator feels participant will not tolerate PES catheter? (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B16. Palliative care or expected to be discharged or transferred to a site not running the trial during the 6 days of PES treatment period? • Expected to be repatriated to a separate organisation. • Expected to be rehabilitated at a separate organisation. • Not likely to be in the treating hospital for at least 14 days. (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B17. Participating in another randomised controlled treatment trial for post-stroke dysphagia? (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)

B18. Pregnant (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B19. Known presence of a pharyngeal pouch (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B20. Investigator believes dysphagia will be short-term e.g. signs of impending recovery in swallowing (Must be No to be eligible)	◯ Yes ◯ No (Choose one answer)
B21. Participant is risk-feeding at time of screening (Must be No to be eligible)	◯ Yes ◯ No

Section C: Eligibility checklist: ⚠ If the participant is NOT eligible - do not proceed.

C1. Is Participant Eligible?

☐ Participant's identifiers A1-A3 must be entered
☐ Inclusion criteria B1-B4 must be YES.
☐ Exclusion criteria B5-B21 must be NO.
☐ B7 NIHSS-1a score for consciousness is NOT (2) Movements to pain nor (3) Postures or unresponsive.

All the above criteria must be satisfied	☐ Participant is eligible.

Section D: Consent (mandatory)

PES on top of guideline-based standard-of-care. (i.e. IN ADDITION TO standard-of-care)
It must be clearly explained, that the PES treatment is an ADDITIONAL treatment to standard-of-care and not a substitute for it.

Protocol violation: Participation without consent, is classified as a protocol violation.

Patients must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice.
The decision regarding participation in the study is entirely voluntary.
The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

D1a. Consent obtained from

Consent is mandatory, no participation in the trial should be allowed without consent.

◯ Participant consent (all nations)
◯ Consultee declaration (England, Wales, Northern Ireland, Germany & Denmark)
◯ Personal legal representative (Scotland, Austria)
◯ Independent physician (England, Wales, Northern Ireland & Austria)
◯ Not Available

If consent was given on behalf of the participant, the participant's consent will be sought if he/ she regains capacity.

D1b. Consent witnessed by a third party. Consent will be witnessed by a third party if the patient lacks the ability to write a signature (e.g., due to dominant hand weakness) or where approval is provided by a consultee by phone.

◯ Yes ◯ No ◯ Not applicable

D1c. Name of the witness.

_____

D2. Signed and dated consent form The participant will receive a copy of the signed and dated form. The original will be retained in the Trial Master File. A second copy will be filed in the participant's medical notes. A signed and dated note made in the notes that informed consent was obtained for the trial.

☐ Participant copy
☐ Original in the Trial Master File
☐ Second copy filed in participant's medical notes
☐ Signed and dated note confirming consent was obtained

Section E: Assessor information

E1a. Is an associate PI involved?

◯ Yes ◯ No ◯ Not applicable

E1b. Name of associate PI

_____
(Associate PI)

E2. Please enter your name

_____
(Assessor)

E3a. What is your professional role?

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

E3b. If "Other", please specify your role

_____
(Professional role)

E4. Does your role involve working on stroke wards?

◯ Yes ◯ No
(Choose one answer)

E5. Please enter your name if you did not collect the information

_____

E6. 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