

# Day 000

Record ID



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

## Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

### Baseline form v1.3

#### (demographics, clinical, imaging)

- ▶ Please check consent form obtained.
- ▶ Please check Eligibility form completed.

### Section A: Participant details

A1. Centre name:

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(Centre)

A2. Participant ID :

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(Participant ID)

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

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

A4. Date of birth (Eligibility: 18 years and over)

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(dd-mm-yyyy ([age\_today\_000] yrs))

A5. Sex

☐ Female ☐ Male  
(Choose one answer)

A6. Ethnicity

☐ Asian, south  
☐ Asian, east/south-east  
☐ Black  
☐ White  
☐ Prefer not to say  
☐ Other  
(Choose one answer)

A6b. If "Other", please specify ethnicity

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## Section B: Clinical details & Stroke

B1. Modified Rankin scale (mRS), premorbid / pre-stroke (Eligibility: mRS not 4/5)

- ☐ No symptoms at all
  - ☐ No significant disability despite symptoms; able to carry out all usual duties and activities
  - ☐ Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
  - ☐ Moderate disability; requiring some help, but able to walk without assistance
  - ☐ Moderately severe disability; unable to walk and attend to bodily needs without assistance
  - ☐ Severe disability; bedridden, incontinent and requiring constant nursing care and attention
  - ☐ Deceased
  - ☐ Withdrawn
- (Choose one answer)

B2. Stroke, previous?

- ☐ Yes   ☐ No
- (Choose one answer)

## Index/presenting stroke details

B3. Date of Stroke (day [age\_stroke\_000])

(Eligibility: within 2-31 days)

(Date DD-MM-YYYY ([stroke\_age\_today\_000] days))

B4. Stroke type (Eligibility: must be IS or ICH stroke)

- ☐ Ischaemic stroke (IS)
  - ☐ Intracerebral haemorrhage (ICH)
- (Choose one answer)

B5. Stroke lesion location.  
e.g, on scanning (NOT side of weakness)

- ☐ Right
  - ☐ Left
  - ☐ Bilateral
  - ☐ Infratentorial (brainstem, cerebellum)
- (Choose one answer)

B6. Stroke syndrome

- ☐ Total anterior circulation (TACS, weakness and/or numbness + dysphasia and/or neglect + hemianopia)
  - ☐ Partial anterior circulation (PACS, not TACS or LACS or POCS)
  - ☐ Lacunar (LACS, weakness and/or numbness in 2 or 3 of face, arm and leg)
  - ☐ Posterior (POCS, isolated hemianopia or cerebellar or brainstem)
- (Choose one answer)

**Section C: In-hospital care up to enrolment**

C1. Date of admission to hospital

\_\_\_\_\_  
(Date DD-MM-YYYY)

C2. Thrombolysis - intravenous alteplase, tenecteplase?

☐ Yes ☐ No  
(Choose one answer)

C3. Intra-arterial therapy? e.g. mechanical thrombectomy

☐ Yes ☐ No  
(Choose one answer)

C4. Neurosurgery - hemocraniectomy?

☐ Yes ☐ No  
(Choose one answer)

C5. Neurosurgery - haemorrhage (evacuation, shunt)?

☐ Yes ☐ No  
(Choose one answer)

C6. Vascular surgery? e.g. carotid endarterectomy/stenting

☐ Yes ☐ No  
(Choose one answer)

C7a. Admission to (neuro-)critical/intensive care unit?

☐ Yes ☐ No  
(Choose one answer)

C7b. Date of admission to ICU

\_\_\_\_\_  
(Date DD-MM-YYYY)

C8a. Received ventilation in ICU?

☐ Yes ☐ No  
(Choose one answer)

C8b. Days ventilated

\_\_\_\_\_  
(Integer 1-30)

C9. Required a tracheotomy/tracheostomy?

☐ Yes ☐ No  
(Choose one answer)**Section D: Clinical state now at time of enrolment**D1. Dysphonia now?  
(Dysphonia is poor/weak voice quality)☐ Yes ☐ No ☐ Not doneD2. Dysarthria now?  
(Dysarthria is slurred speech)☐ Yes ☐ No ☐ Not done

D3. Gag reflex

☐ Normal ☐ Abnormal  
☐ Not done

D4. Abnormal spontaneous cough?

☐ Yes ☐ No ☐ Not done

D5. Cough after water swallow?

☐ Yes ☐ No  
(Choose one answer)

D6. Voice change after water swallow?

☐ Yes ☐ No  
(Choose one answer)

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D7. Calculated aspiration score

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(Calculated)

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D8. Weight (or estimated weight) in kilos

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(Number (30-200) kg)

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D9. Height (or estimated height) in meter

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(Number (1.0-2.2) m)

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D10. Body mass index (BMI)

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(BMI = Weight / height<sup>2</sup> )

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### Section E: Admission CT/MRI scan results

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E1a. Type of admission scan

☐ CT scan   ☐ MRI scan  
☐ No scan  
(Choose one answer)

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E1b. Why was admission CT/MRI scan not done?

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(Free text)

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E2. Date of admission scan

---

(Date DD-MM-YYYY)

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E3. What was the admission scan diagnosis?

Please review the scan report.

☐ Normal scan/no lesion seen that explains presentation  
☐ Infarct/ischaemic stroke  
☐ Infarct with haemorrhagic transformation of infarct (HTI)  
☐ Primary/spontaneous intracerebral haemorrhage (ICH)  
☐ Sub-arachnoid haemorrhage (primary)  
☐ Non stroke lesion that explains presentation, e.g. tumour, abscess  
(Choose one answer)

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E4. Was index stroke visible on admission scan?

Please review the scan report.

☐ Yes   ☐ No  
(Choose one answer)

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E5. Was the lesion on scan compatible with the presenting stroke?

☐ Yes   ☐ No  
(Choose one answer)

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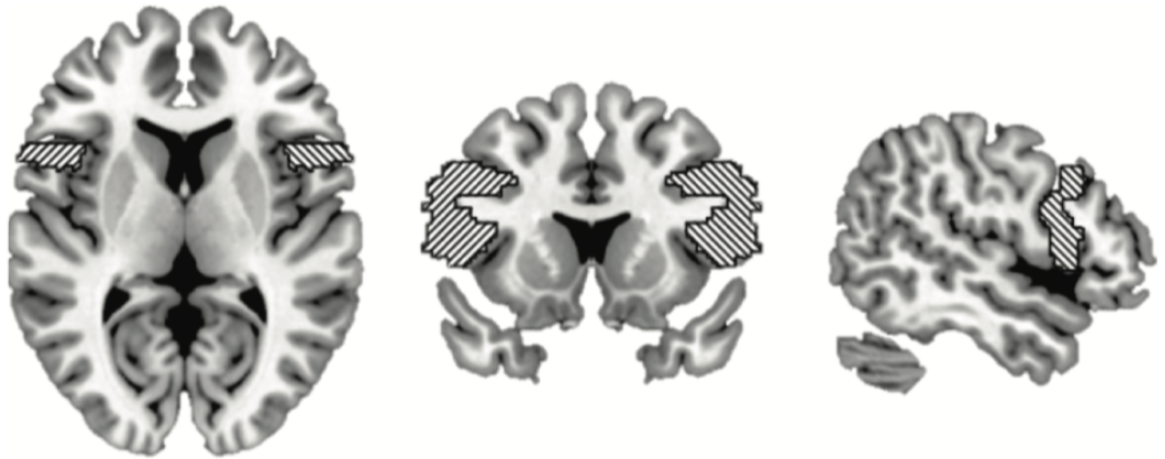
E6a. Did the stroke involve the frontal operculum on the admission scan? Please review the scan report and ask the PI.

☐ Yes   ☐ No

E6b. Schematic of where the frontal operculum is [Galovic et al. JAMA Neurology 11 Feb 2019])  
[https://stroke.nottingham.ac.uk/pheast/images/frontal\\_operculum.png](https://stroke.nottingham.ac.uk/pheast/images/frontal_operculum.png)

**Stroke location**

- ☐ **0 pts**      No lesion of the frontal operculum
- ☐ **1 pt**      Lesion of the frontal operculum



E7. Was there evidence on the admission scan of mass effect?

☐ Yes   ☐ No  
(Choose one answer)

Please review the scan report.

E8. Was there evidence on the admission scan of cerebral atrophy?

☐ Yes   ☐ No  
(Choose one answer)

Please review the scan report.

E9. Was there evidence on the admission scan of periventricular white matter disease-lucency/leukoaraiosis?

☐ Yes   ☐ No  
(Choose one answer)

Please review the scan report.

E10. Was there evidence on the admission scan of any previous stroke(s)?

☐ Yes   ☐ No  
(Choose one answer)

Please review the scan report.

E11. Admission brain/head scan report by hospital radiologist (or equivalent)

Please cut and paste full report.

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**Section F: Follow-up CT/MRI scan results. If there is more than one follow-up scan prior to enrolment, please choose one from 2-10 days after stroke and ideally a MRI rather than CT scan.**

F1. Type of follow-up scan

☐ CT scan   ☐ MRI scan  
☐ No scan  
(Choose one answer)

F2. Date of follow-up scan

\_\_\_\_\_  
(Date DD-MM-YYYY)

F3a. Did the stroke involve the frontal operculum on the follow-up scan?

☐ Yes   ☐ No

Please review the scan report and ask the PI.

Please refer to E6b for a schematic of where the frontal operculum is [Galovic et al. JAMA Neurology 11 Feb 2019])

F4. Follow-up brain/head scan report by hospital radiologist (or equivalent)

Please cut and paste full report.

If there are several scans, please choose a brain scan about 7 days after stroke onset, preferably based on MRI rather than CT

**Section G: Eligibility check & other stroke research trials**

⚠ **If the participant does NOT satisfy the eligibility criteria - review the Eligibility CRF.**

G1. Is Participant Eligible?

G2. Already in any hyper-acute or acute stroke research trial(s)?

☐ MAPS-2  
☐ ReCAST-3  
☐ TICH-3  
☐ ENOS-2  
☐ ProFATE  
☐ MACE-ICH

**Section H: Assessor information**

H1. Please enter the name of the person who collected the information

\_\_\_\_\_  
(Collected information)

H2a. What is his/her professional role?

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

H2b. If "Other", please specify role

\_\_\_\_\_  
(Professional role)

H3. Does his/her role involve working on stroke wards?

- ☐ Yes ☐ No  
(Choose one answer)

H4. Please enter your name if you did not collect the information Name of person entering the data, if it differs from the assessor.

\* Blinded assessors often collect but do not enter the data as it could unblind them.

\_\_\_\_\_  
(Filling the form)

H5. Please sign the form

\_\_\_\_\_  
(Signature)

## Section I: Randomisation

I1. Date randomisation

\_\_\_\_\_  
(The date will be filled-in automatically at randomisation)

I2. Age

\_\_\_\_\_  
(The age will be auto calculated at randomisation)

I3. Onset to randomisation (days)

\_\_\_\_\_  
(Calculated 2-31)

## 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