Withdrawal

Record ID _____

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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

Withdrawal from trial form v1.0

▶ Please check consent form obtained.

Section A: Participant details

A1. Center name : _____

A2. Participant ID : _____

A3. Participant initials : _____

Section B: Withdrawal details

Discontinuation and withdrawal

Once enrolled, participants, their relative (if the participant still lacks capacity), the site PI, or the CI, may:

• Discontinue further PES, e.g., if they suffer an adverse event and decide they no longer want PES;

• Discontinue further PES, e.g., removal of catheter before PES treatment is finished only if patient is ready for discharge, or unless the patient cannot tolerate the tube or removes it.

• Temporarily discontinue follow-up, e.g., refuse follow-up at a particular timepoint;

• Withdraw from the trial, including from further PES (if still in the treatment phase) and from all further follow-up, e.g., if they withdraw consent from the trial. Participants must be withdrawn from study if they withdraw consent.

Inform participant

Site and trial staff may discuss with the participant the importance of collecting the primary outcome and so limiting the effect of withdrawal. Participants should be told that withdrawal:
• Will not affect their future care.
• Will not affect data collected up to the date of withdrawal, i.e., it cannot be erased and may still be used in the final analysis.

Lost to follow-up

Lost to follow-up

Participants will be deemed to be lost to follow-up once at least four attempts to make contact, e.g., involving phone calls, letters, have been fruitless.

Withdrawal details

B1. Date of withdrawal:

_____
(Date DD-MM-YYYY)

B2. Withdrawal type:

Withdraw from trial and all further follow-up.

including from further PES (if still in the treatment phase)

B4. Withdrawn before or after receiving treatment(s)

◯ Before treatment
◯ During treatment
◯ After treatment
◯ Not known
◯ Not applicable

B5a. Withdrawn by

◯ Participant
◯ Principal Investigator or delegated investigator
◯ CI
◯ Family (if they lack capacity) or clinical team
◯ Other

B5b. If "Other", please specify withdrawn by whom

_____

Withdrawal reason

B6. Withdraw as a result of an SAE

◯ Yes ◯ No

B7a. Reason for withdrawal:

◯ Unhappy with the study
◯ Unhappy with the the consent process
◯ Unhappy with the treatment allocation
◯ Unhappy with the treatment allocation being blinded
◯ Unhappy with the side effects of medications
◯ Fatigue and unhappiness with standard of care
◯ Moving out of area
◯ Lack of time or additional unforeseen responsibilities
◯ Loss of capacity
◯ Cognitive decline
◯ Co-morbities
◯ Withdraw from further follow-ups
◯ Withdraw from trial
◯ Lost to follow-up
◯ Withdraw as a result of an SAE
◯ Participant does not wish to provide a reason
◯ Other
(Choose one answer)

B7b. If "Other", please specify withdrawal reason

_____

More details...

B8. Comments

Section C: Assessor information

C1. Please enter your name

_____

C2a. What is your professional role?

◯ Doctor
◯ Research coordinator
◯ Nurse, clinical
◯ Research nurse
◯ Physiotherapist
◯ Occupation therapist
◯ Speech & Language therapist
◯ Other

C2b. If "Other", please specify your role

_____

C3. Does your role involve working on stroke wards? ◯ Yes ◯ No

C4. Please enter your name if you did not collect the information

_____

C5. Please sign the form

_____
(✍ Signature)

⚠ Please Sign the form.

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