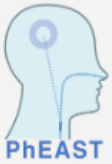
SWAT

Record ID

_____
(REDCap auto generated)



Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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

SWAT form v1.3

Section A: Contact person

A1. Who was contacted

_____

A2a. Role of person contacted

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

A2b. If "Other", please specify the role

_____

A3. Date of contact

_____
(dd-mm-yyyy)

A4. Time of contact

_____
(hh:mm)

A5. Please log time in minutes spent talking to the site

_____

Section B: Trigger for additional support

PES on top of guideline-based standard-of-care. (i.e. IN ADDITION TO standard-of-care)
• PES will be administered on days 1-6 using a commercial catheter with integral feeding tube.
• PES involves six daily 10 minute treatments at 5 Hz; threshold and tolerability currents will be assessed and the treatment current set at threshold + 0.75 x (tolerability - threshold) with current generated by a base-station.
• Dosing levels will be monitored, and sites informed if the stimulation current is too low, i.e. < 20 mA;
• The catheter will be replaced if pulled out or removed before 6 treatments have been administered.

Participant details

A1. Centre name:

_____
(Centre)

B2. Participant ID :

_____
(Participant ID)

B3. Participant initials :

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

B4. Associated treatment

◯ PES treatment 1
◯ PES treatment 2
◯ PES treatment 3
◯ PES treatment 4
◯ PES treatment 5
◯ PES treatment 6

B5a. Trigger

◯ Treatment stimulation too short, < 9 mins 50 secs
◯ Treatment stimulation level too low, < 20 mA AND stimulation level lower than calculated level
◯ Treatment stimulation level too low, < 20 mA
◯ Treatment stimulation level lower than calculated level
◯ Other

B5b. If "Other", please specify trigger

_____

Section C: Reason

C1a. Reasons given for low levels

- ◯ Participant's calculated stimulation level < 20mA.
- ◯ Participant could not tolerate calculated stimulation level
- ◯ Participant concerned about using a higher stimulation level
- ◯ Treater concerned about using a higher stimulation level
- ◯ Family concerned about using a higher stimulation level
- ◯ Untrained treater
- ◯ Equipment/device problems during treatment - Please also complete Device deficiency form
- ◯ Participant had low tolerance level
- ◯ Safety button used to stop PES
- ◯ Other

C1b. If "Other", please specify

_____

C2. Does reason match that provided at time of treatment?

◯ Yes ◯ No

Section D: Training

D1. Training route

- ☐ Face to face
- ☐ Telephone
- ☐ Video
- ☐ Email

D2a. Training type

- ☐ Reminder on minimum stimulation level
- ☐ Reminder on determining threshold and tolerance levels (e.g. look for facial evidence of discomfort)
- ☐ Repeat guidance on PES rationale - reason for higher levels (e.g. neutral STEPS trial)
- ☐ Live Q&A session
- ☐ Written Q&A response
- ☐ Other

D2b. If "Other", please specify

_____

Section E: Additional information

E1. Additional information

_____

Section F: Trainer

F1. Please enter the name of the person doing the training

_____

F2a. Role of person doing the training

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

F2b. If "Other", please specify the role

_____

F3. Please sign the form

_____

(✍ Signature)

F4. Date/time training completed

_____

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

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'? as specified above, OR There are specific flags set or values checked programatically.

- ◯ Yes
- ◯ No

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