

SWAT

Record ID _____



Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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

SWAT form v1.2

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 once only if pulled out before 3 treatments have been administered.

Participant details

B1. Center name :

B2. Participant ID :

B3. Participant initials :

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'?

 Yes No

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