PES treatment 6

Record ID _____

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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

PES Sixth/last treatment form v1.4

▶ Please check consent form obtained.
▶ Please check PES 1-5 treatment forms are completed.

Section A: Participant details

A1. Centre name:

_____
(Centre)

A2. Participant ID :

_____
(Participant ID)

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

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

A4a. Follow-up status for 6th treatment

- ◯ Randomised to control
- ◯ Agreed to treatment 6
- ◯ Refused treatment 6
- ◯ Withdrawn from trial and all treatments and follow-ups
- ◯ Temporarily discontinue
- ◯ Discontinue further PES
- ◯ Discharged
- ◯ Died

A4b. If treatment refused, please specify reason for refusal

_____

Section B: Sixth PES treatment

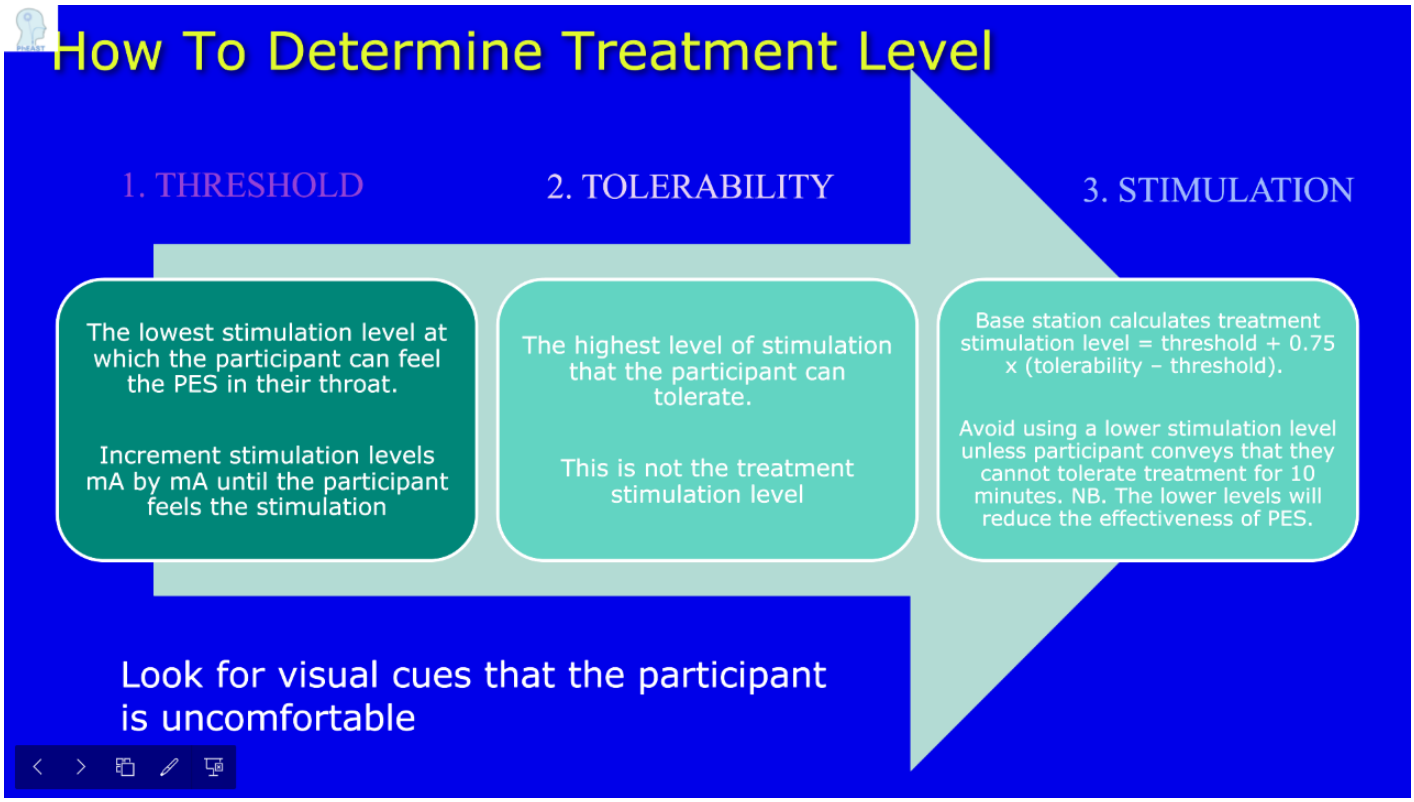
PES on top of guideline-based standard-of-care. (i.e. IN ADDITION TO standard-of-care)• PES will be administered on days 1-6 using a commercial catheter with integral feeding tube. • PES involves six daily 10 minute treatments at 5 Hz; threshold and tolerability currents will be assessed and the treatment 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.

Potential causes of over treatment include PES given:• For more than 10 minutes - the base station prevents this;• For more than 6 days - the device catheters prevent this;• At too high a current - the participant would indicate this as severe discomfort. Correct calculation of treatment current from threshold and tolerance currents will prevent this.In each case, turning the base station off will prevent over-treatment.

Over or under stimulation and deviations from recommended current or times will be monitored:• Difference threshold - tolerance < 8mA• Delivered stimulation < 20 mA• Delivered stimulation not within 2 mA of calculated stimulation level• Calculated - delivered stimulation level > 2 mA• Delivered stimulation differs from calculated stimulation level• Duration is too short, i.e. < 9:50 minutes• Duration is too long, i.e. > 10:00 minutes• PES treatment levels cannot vary by > 30% between treatment sessions.

How to determine the treatment level?

How to determine the treatment level



Was the treatment given?

B1a. Was the sixth PES treatment given? ◯ Yes ◯ No

B1b. If not, why was the 6th PES treatment not given?

- ◯ Randomised to control
- ◯ Catheter could not be inserted or position verified
- ◯ Discharged home or to another institution
- ◯ Died
- ◯ Refused this PES treatment
- ◯ Stopped PES treatment altogether
- ◯ Withdrawn from trial treatment and follow-up
- ◯ Device/equipment failure
- ◯ Safety button used to stop PES
- ◯ Removal of catheter before PES treatment is finished
- ◯ Patient cannot tolerate the tube or removes it
- ◯ Temporarily discontinue the 6 days of PES, e.g., if they transiently deteriorate;
- ◯ Other

B1c. If "Other", please specify reason for treatment not given

_____

PES treatment dates

B3. Date of sixth PES treatment?

① [pes_date_1], ② [pes_date_2], ③ [pes_date_3], ④ [pes_date_4], ⑤ [pes_date_5]

_____
(Date DD-MM-YYYY)

Threshold - lowest stimulation level

B4. Sixth PES threshold mA? (lowest stimulation level)

_____
(Integer 1-50)

The lowest stimulation level at which the participant can feel the PES in their throat.

Increment stimulation levels mA by mA until the participant feels the stimulation.

Look for visual cues that the participant is uncomfortable.

Tolerance - highest stimulation level

B5. Sixth PES tolerance mA? (highest stimulation level)

_____
(Integer 1-50)

The highest level of stimulation that the participant can tolerate. Tolerability level is best assessed by watching the participants face and body for evidence of discomfort rather than repeatedly asking if the current level is excessive (which often leads to lower stimulation levels).

Base station calculated suggested stimulation level

B6. Sixth PES calculated stimulation level mA?
(as per displayed on the device - expected to be ≃ [pes_calculated_auto_6] mA)
① [pes_calculated_1] mA ② [pes_calculated_2] mA
③ [pes_calculated_3] mA ④ [pes_calculated_4] mA
⑤ [pes_calculated_5] mA

The base station will calculate the treatment stimulation level from the lowest threshold and highest tolerability levels.

Avoid using a lower stimulation level unless the participant conveys that they cannot tolerate treatment for 10 minutes. (NB. The lower levels will reduce the effectiveness of PES).

_____

_____
(mA (as displayed on the device))

Delivered stimulation - expected to be ≥ 20 mA and within 2 mA of calculated level

B7. Sixth PES stimulation level mA?

_____
(Integer 1-50)

B8a. Does the actual treatment level differ from the calculated level?

◯ Yes ◯ No

B8b. Please explain why actual stimulation differs from the calculated stimulation

◯ Participant's calculated stimulation level < 20mA.
◯ Participant could not tolerate calculated stimulation level
◯ Participant worried about using a higher stimulation level
◯ Treater worried about using a higher stimulation level
◯ Family worried about using a higher stimulation level
◯ Change of staff, i.e. person had not been trained
◯ Equipment/device problems during treatment - Please also complete Device deficiency form
◯ Participant had low tolerance level
◯ Safety button used to stop PES - Please notify manufacturer
◯ Other

B8c. If "Other", please specify reason why stimulation differs

_____

Treatment duration - expected to be 10:00 minutes.

B9a. Sixth PES duration?

(09:50 - 10:00 minutes)

_____
(Time (minutes:seconds))

B9b. Please explain why actual treatment not done for 10:00 min.

(Treatment should be between 9:50 and 10:00 minutes, ideally the full 10:00 minutes)

◯ Participant could not tolerate calculated stimulation level
◯ Change of staff, i.e. person had not been trained
◯ Equipment/device problems during treatment - Please also complete Device deficiency form
◯ Participant had low tolerance level
◯ Safety button used to stop PES
◯ Other

B9c. If "Other", please specify reason why full 10:00 minutes not done

_____

LOT numbers and replaced catheter(s)

B10a. How many PES catheters were used?
(Up to 6)

([nr_lots_total_6] distinct LOT numbers entered on the CRFs)

_____
(0-6)

B10b. Date of insertion of new catheter?
First catheter insertion date was [pes_date_catheter1_1]

_____
(Date DD-MM-YYYY)

B10c. What is the LOT number of the current treatment catheter?
First catheter LOT number was [pes_catheter_lotno_1]

_____

B11. What is the current base station serial number?
First base station serial number was [pes_basestation_serialno_1]

_____

Section C: Device deficiency

C1a. Were there any equipment/device problems during treatment 6?

We have a legal duty to report device or equipment failure to the manufacturer immediately.

◯ Yes ◯ No ◯ Not applicable

C1b. Description of device or equipment failure in any of treatment 1 to 6.

_____

For example:

▶ First PES treatment not given because of device or equipment failure.

▶ Stimulation level differs from calculated level because of device or equipment failure.

▶ Treatment not done for 10:00 because of device or equipment failure.

▶ Reported device or equipment failure.

▶ Reported more than 2 catheters used.

✍ If there is any equipment/device problems, including using more than 2 catheters, during the treatment, complete the Device deficiency form as soon as possible.

NB. Complete the protocol deviation or SAE forms if applicable.

Section D: Urgent safety measure: (safety button used to stop PES)

D1. Any urgent safety measures will be conveyed as soon as possible to the sponsor and device manufacturer.

Please fill in the device defficiency and protocol deviation CRFs and report an SAE should one be applicable.

D1a. Description of Urgent safety measure (Safety button used to stop PES) in any of treatement 1 to 6

Any urgent safety measures will be conveyed as soon as possible to the sponsor and device manufacturer.

Please fill in the device defficiency and protocol deviation CRFs and report an SAE should one be applicable.

For example:

▶ First PES treatment not given because the safety button was used.

▶ Stimulation level differs from calculated level because the safety button was used.

▶ Treatment not done for 10:00 because the safety button was used.

Section E: SWAT and reportable event

E1. More details on possible S.W.A.T. or reportable event

⚠ Stimulation level or duration of treatment is too low, high or not within the tolerance range.

Potential causes are:

- Difference threshold - tolerance < 8mA
- Delivered stimulation < 20 mA
- Delivered stimulation not within 2 mA of calculated stimulation level
- Calculated - delivered stimulation level > 2 mA
- Delivered stimulation differs from calculated stimulation level
- Duration is too short, i.e. < 9:50 minutes
- Duration is too long, i.e. > 10:00 minutes
- PES treatment levels cannot vary by >30% between treatment sessions.

Section F: Ease of use.

F1. Insertion of catheter

◯ very difficult
◯ difficult
◯ moderately difficult
◯ average
◯ moderately easy
◯ easy
◯ very easy

F2. Use of guidewire

◯ very difficult
◯ difficult
◯ moderately difficult
◯ average
◯ moderately easy
◯ easy
◯ very easy

F3. Use of oral; guide

◯ very difficult
◯ difficult
◯ moderately difficult
◯ average
◯ moderately easy
◯ easy
◯ very easy

Section G: Summary of PES treatments

G1. Base station serial number and catheter details:

• First base station serial number
• First catheter insertion date
• First Catheter LOT number

• Last base station serial number
• Last catheter insertion date
• Last Catheter LOT number

G2. Treatment details:

• Daily detail of treatments

✍ If there is any equipment/device problems during the treatment, complete the Device deficiency form as soon as possible.

We have a legal duty to report these to the manufacturer immediately.

G3. Device deficiency form

• Date
• Timing
• Component
• Catheter LOT number
• Base station serial number
• Equipment/ device problem
• Failure type
• Description
• Related to
• Associated to SAE
• Return to manufacturer

Section H: Day 6 treater information.

Please note: The person(s) providing treatment must not perform subsequent assessments

H1. Please enter your name?

_____
(Person giving the treatment)

H2. What is your professional role?

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

H2b. If "Other", please specify your role

_____

H3. Does your role involve working on stroke wards?

◯ Yes ◯ No

H4. Please enter your name if you did not do the treatment

_____

H5. 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