Protocol Deviation

Record ID _____

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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

Protocol Deviation form v1.0

▶ Please check consent form obtained.

Section A: Participant details

A1. Center name : _____

A2. Participant ID : _____

A3. Participant initials : _____

Section C: Protocol deviation details

Protocol Deviation:

These are minor deviations from the protocol that affect the conduct of the trial in a minor way. This includes any deviation from the trial protocol that is not listed as a Protocol Violation.

Treatment protocol:

Delivered stimulation is expected to be >= 20 mA and the same as calculated stimulation level.
Treatment time expected to be 10:00 min. Under or over treatment must be reported.

Over treatment:
• 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.

Urgent safety measures:
PES treatment may be stopped at any time by the press of a button on the control base station. Any urgent safety measures will be conveyed as soon as possible to the sponsor and device manufacturer.

Protocol Deviation

C1. Date of event:

_____
(Date DD-MM-YYYY)

C2a. Associated event or CRF

- ◯ PES treatment 1
- ◯ PES treatment 2
- ◯ PES treatment 3
- ◯ PES treatment 4
- ◯ PES treatment 5
- ◯ PES treatment 6
- ◯ Day 14 primary outcome
- ◯ Day 90 follow-up
- ◯ Day 180 follow-up
- ◯ Day 365 follow-up
- ◯ Other

C2b. If "Other", please specify which CRF

_____

C3a. Type of protocol deviation

Enter full explanation below

- ◯ Baseline form not complete
- ◯ Follow up form not complete
- ◯ Follow up form completed outside of time window
- ◯ Delivered stimulation level < 20 mA
- ◯ Delivered stimulation level < calculated stimulation
- ◯ Time of treatment too short, i.e. < 9 mns 50sec
- ◯ Time of treatment too long, i.e. > 10 mns - the base station prevents this;
- ◯ Participant treated at +/-2 from calculated stimulation
- ◯ Stimulation level is too low, i.e. threshold - tolerance < 8mA
- ◯ PES should not be used in the presence of any active implanted electrical device, e.g., cochlear implant, implantable cardioverter-defibrillator (ICD), permanent pacemaker.
- ◯ DSRS not >3 at Day 014
- ◯ Other stimulatory techniques for dysphagia (neuromuscular electrical stimulation, transcranial magnetic stimulation, transcranial direct current stimulation) should not be used.
- ◯ Participant not given 3 consecutive treatments.
- ◯ Less than 3 consecutive treatments before having a break
- ◯ More than one treatment break
- ◯ PES given for more than 6 days - the device catheters prevent this;
- ◯ PES given 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
- ◯ Safety button used to stop PES
- ◯ PES treatment levels vary by >30% between treatment sessions
- ◯ Other

(Choose one answer)

C3b. Full explanation / comments

_____

C4. Device or equipment related deviation ◯ Yes ◯ No

C5. Urgent safety measure related deviation.
(e.g. safety button used to stop PES) _____
(1 = Yes, 0 = No)

Section D: Assessor information.

D1. Please enter your name _____

D2a. What is your professional role?
◯ Doctor
◯ Research coordinator
◯ Nurse, clinical
◯ Research nurse
◯ Physiotherapist
◯ Occupation therapist
◯ Speech & Language therapist
◯ Other

D2b. If "Other", please specify your role _____

D3. Does your role involve working on stroke wards? ◯ Yes ◯ No

D4. Please enter your name if you did not collect the information _____

D5. 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