

Protocol Violation

Record ID



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

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

Protocol violation form v1.2

► Please check consent form obtained.

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 (-))

Section C: Protocol violation details

Protocol violation:

These are a major deviation from the trial protocol, for example where a participant is enrolled in spite of not fulfilling all the inclusion and exclusion criteria, or where deviations from the protocol could affect participant safety, the trial delivery or interpretation significantly. Listed protocol violations are:

1. Treatment without consent.
2. Treatment but ineligible.
3. Non-reporting of primary outcome measure.
4. Non-reporting of serious adverse event (SAE), serious adverse device event (SADE), serious unanticipated adverse device event (SUADE).

All protocol violations must be reported immediately to the Chief Investigator, via the online electronic case report form. The CI will notify the Sponsor if a violation has an impact on participant safety or integrity of the trial data. The Sponsor will advise on appropriate measures to address the occurrence, which may include reporting of a serious GCP breach, internal audit of the trial and seeking counsel of the trial committees.

Protocol Violation

C1. Date of event:

(Date DD-MM-YYYY)

C2a. Type of protocol violation

Enter full explanation below

- Treatment given without consent
- Treatment given when ineligible
- Primary outcome measure not reported
- SAE, SADE or USADE not reported where appropriate
- Enrolled without meeting inclusion/exclusion criteria
- Patient safety at risk
- Other electrical/magnetic stimulation device used
- Any other major violation of the trial protocol

C2b. If "Other", please specify protocol violation type

C3. Full explanation / comments

C4. Device or equipment related deviation

 Yes NoC5. Urgent safety measure related deviation.
(e.g. safety button used to stop PES) Yes 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
- (Choose one answer)

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