

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial

PhEAST

We are now recruiting!



3 Participants recruited!



Recent Green Lights



Bath - Royal United Hospital Bath NHS Foundation Trust
Nottingham - Queen's Medical Centre
Poole & Bournemouth - University Hospitals Dorset
Sunderland - Sunderland Royal Hospital

Trial Training:

There are two sets of trial training for PhEAST:

- Virtual SIV (conducted by the UoN Stroke trials team) Approx 1.5 hours
- Face to face equipment training (conducted by Phagenesis) Approx 2 hours

Please get in touch with us if you're ready to schedule your PhEAST trial training:

Pheast@nottingham.ac.uk
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Amendments:

Approved amendments:

MA/01/22 - Approved 16/02/2022
MA/02/22 - Approved 22/02/2022
MA/03/22 - Approved 11/03/2022
SA/01/22 - Approved 17/03/2022
MA/04/22 - Approved 17/03/2022

Common FAQs:

What is the planned recruitment end date and study end date?

Recruitment end date: 30th November 2024

Study end date: 30th February 2025

Where can I find the trial documents?

All trial documents for your site file can be found and downloaded at
<https://stroke.nottingham.ac.uk/pheast/docs/>

Who can consent patients in PhEAST?

Both medics and non-medics may take consent. Consenting investigators must explain the trial to patients, elaborate on the risks and potential benefits and be able to answer any trial-specific questions.

Is the device for implementing the Pharyngeal Electrical Stimulation CE marked?

Yes. The device is being used for the purpose it was designed for, which allows for 3-6 days of stimulation.

If the Phagenyx nasogastric catheter is pulled out, can it be replaced?

The catheter can be replaced once with a new catheter. There is a limited supply of additional catheters therefore it is important to ensure the catheter stays in situ.

Can the trial catheters be used as standard NGTs?

Yes, the Phagenesis catheters can be used for enteral feeding.

Who can complete the day 14 follow ups?

A blinded SLT must complete a bedside assessment, the SLT can they go on to do the rest of the PhEAST follow up, or a blinded researcher can take over. Please refer to WPD 008 Blinding for a more detailed overview of blinding in the PhEAST trial.

How do I get a new member of staff access to the online delegation log?

Please get the new member of staff to complete the trial training (review of the SIV slides / recording of the SIV). If they have any queries they can email the trial team. Once they have signed the SIV log, they need to send this to the trial team who can then invite them to the database where the online delegation log is stored.

Do SLTs only completing the bedside swallow assessments need GCP training?

No - if they are only completing the bedside swallow assessments then they just need to complete the trial training and sign on to the online delegation log.