PhEAST – Frequently Asked Questions

Study Set Up:

Q: Can the PI for PhEAST be a non-medic?
A. Yes, for example a speech and language therapist, specialist nurse, as they can explain the benefit/risks of the intervention. It is advised to have a medic on the delegation log who can assist with SAEs

Q: Are any additional blood samples for laboratory analysis required in PhEAST?
A: No additional blood tests are required. The results of blood tests performed as per standard of care relating to chest infections such as pneumonia will be collected.

Q: Do 'treaters' need to be GCP trained and have a Research CV?
A: Yes, staff members who are treating participants need to have their GCP, research CV and attend the SIV and face to face training.

Q: Do speech and language therapists who are only completing blinded bedside assessments need to be GCP trained?
A: No, as they are only completing their normal clinical role our sponsor has confirmed they do not need GCP training. However, they should attend the SIV and be signed on to the delegation log.

Q: Who is liable for the Phagenesis base station?
A: For the duration of the trial, sites will have their own base station under a loan agreement from the manufacturer, Phagenesis. In terms of the Loan agreement, the site is liable for any loss or damage arising out of or in connection with any negligence, misuse or mishandling of the device(s).

Q: What constitutes a recruit?
A: Once you have randomised a participant, this will count as a recruit. The catheter should be inserted, and treatment should begin as soon as possible after randomisation, if randomised to PES.

Q: What is the role of the SLT in this trial?
A: This varies by site. Eg. In Derby SLT are heavily involved in terms of helping with consenting and doing the treatment. In Nottingham the PI is SLT and research nurses do the treatment and assessment so depends on your research team.

Eligibility:

Q: Can we recruit participants who have COVID-19?

A: Yes, participants withCOVID-19 can be recruited as long as they do not require more than 35% of oxygen. Researchers must follow their hospital policies and procedures with regards to PPE, and ensure the base station is adequately cleaned between participants.

Q: If a participant has a further stroke, can they remain in the trial?
A: Yes, please report this via the E-CRF.

Q:If a patient has already participated in the PhEAST trial, could they participate again if they had a recurrent stroke?
A:No - participants can only be enrolled into the PhEAST trial once, unless they withdraw consent and wish to participate again within the time frame (same stroke).

Q: If patients are receiving upper limb NMES, can they be recruited into the PhEAST trial?
A: Yes, NMES is only an exclusion when it is being used to treat dysphagia.

Q: Can participants who are awaiting VFS / FEES to assess swallow be entered into the trial?
A: If you are able to make a clinical diagnosis of dysphagia then yes. If you need to await VFS / FEES to get a diagnosis of dysphagia then please await the results of these before entering into the trial.

Q: What constitutes a FOIS score of 2?
A: FOIS of 2 is up to and including 15 teaspoons of food / drink per day. FOIS 3 is still NG dependent, but above 15 teaspoons a day. Please see the trial manual for further guidance.

Q: Can we include patients who have purely oral dysphagia?
A: Yes.

Q: Can eligibility be confirmed by an SLT / research nurse?
A: Yes.

Q: Can we include patients who are experiencing total sensory loss?

A: Yes, these patients are great candidates to potentially receive PES.

Consent:

Q: Who can take consent?
A: Consent can be taken by NIHR CRN nurses/co-ordinators to recruit, all must be GCP-trained and on the delegation log. Written informed consent will be sought but a documented, witnessed mark or oral consent due to physical inability to sign is permitted.

Q: Can we use next of kin consent?
A: If a patient does not have capacity, you can attempt the consent of a consultee. Please use the correct paperwork for this. If the participant then regains capacity, you must attempt re-consent of the participant.

Q: Do we need to consent an informant even if the main trial participant has capacity?
A: Yes please, as the informants give us a different perspective on the participants' cognition. Please see the cognition sub-study WPD for more details on informant consent.

Treatment:

Q: Is the device for implementing the Pharyngeal Electrical Stimulation CE marked?
A. Yes. The device is being used for the purpose it was designed for, which allows for 3-6 days of stimulation.

Q: If the Phagenyx nasogastric catheter is pulled out, can it be replaced?
A: 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. Treatment will be stopped early if the participant is ready for discharge.

Q: Can the trial catheters be used as standard NGTs?
A: Yes

Q: Can you fit a bridle to the trial catheters?
A: Yes – size 12F.

Q: Do staff that insert catheters have to be GCP trained?
A: No, this can be anyone who is competent in inserting NGTs. Training is offered by the Phagenesis team for staff who insert catheters, although this is not mandatory. It is useful for a member of staff who has attended the Phagenesis training to be around at this time.

Q: Can the PI be a treater?
A: Yes

Q: Is the trial catheter MRI compatible?
A: No. If a potential participant needs MRI to confirm a stroke, please wait until after they have had this done to recruit them into the PhEAST trial. If a participant needs an MRI scan whilst undergoing the treatment, the catheter will need removing and will not be replaced.

Q:Who can deliver the PES treatment?
A:Anyone who has had the Phagenesis face to face training. This could be an SLT, research nurse or research coordinator.

Q:Can we treat two participants at the same time?
A:Yes, the catheters have special codes which when linked to the base station recognise which participant you are treating. Please follow your local policies and procedures with regards to cleaning the base station between participants.

Q:How soon after consent should we randomise, and how soon after randomisation should we treat (if randomised to PES)?
A:Please randomise and treat (if randomised to PES) as soon as possible after the consent process. If a long gap if left between, then participants may return to oral food and drink, or deteriorate, and treatment will not happen.

Q: How do I know when the participant has reached their tolerability level before treatment?
A: We are looking for a body sign or twitch at which point the current is uncomfortable but not painful rather than a verbal response. It is important that the maximum current possible is supplied to the patient for maximum benefit. What we do know from previous trials if we undertreat then this method does not appear to work. So we suggest aim for as high current as possible and try not to ask 'how is it' or 'does it hurt?' and look for non-verbal responses instead.

Q: Can we run feed through the trial catheter whilst administering treatment?
A: No, please stop feed whilst administering treatment. It can remain connected to the stand though.

Q: How many treatments are given in total?
A: 6 treatments are given in total, one a day, for six days. Please refer to the treatment schedule in the trial protocol or trial manual for more advice on treatment breaks.

Q: Can you provide advice on how to keep the trial catheters in?
A: Please consider using a bridle or mitts (with correct DOLs in place) if you think a patient may pull them out.

Q: Will we get any support with our first treatment?
A: Yes, Phagenesis offer to remotely support for your first participant randomsied to PES. When this happens, the trial manager will liaise with you and Phagenesis to arrange this.

Training:

Q: Will training be given for the Pharyngeal Electrical Stimulation device?
A. The company supplying the device (Phagenesis Ltd) will provide in-person training to each individual site at set-up. In addition, all trial detail can be found within the trial manual for reference. A member of the central co-ordinating centre at STU Nottingham will be dedicated to this trial and will be able to answer any queries.

Q: Will we have an SIV?
A: Yes, all sites have a virtual SIV, which takes approximately 1.5 hours. This is in addition to the face to face training you will receive from Phagenesis.

Q: How long does the Phagenesis device training take? A:
This takes approx. 1.5 – 2 hours

Q: Can we get additional staff trained up whilst the trial is ongoing?
A: Please submit any additional training needs to the clinical trial manager

Q: If I've received the Phagenesis device training, can I then go on to train other members of staff on the use of the device?
A: No, all device training must be delivered by the Phagenesis trainers.

Database:

Q: How do we print off SAE forms, so that the PI can countersign these?
A: There is an option on RedCap to download a PDF of the SAE form. This needs to be printed out each time you record an SAE and must always be countersigned by the trial PI. You can then save the paper copy in the site file.

Q:Where can I find the trial documents?
A:All trial documents for your site file can be found and downloaded at https://stroke.nottingham.ac.uk/pheast/docs/

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

Q: Do the cognition CRFs need to be filled in prior to randomisation?
A: Ideally yes, so that all CRFs are complete. However, if you are tight on time you can complete them after randomisation, but please do as soon as possible afterwards.

Q: How do I upload documents to the secure vault?
A: Access supporting site from the left hand side of Redcap, you can then upload documents for each participant. Please see the Document Upload WPD for more assistance on this. They must be uploaded within 24 hours of consent for the central trial team to review.

Follow Ups:

Q:Who can complete the day 14 follow ups?
A: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.

Q: If a participant is discharged or sent to another hospital prior to day 14 follow up, how do we go about completing it?
A: If discharged home, please telephone and complete as much of the follow up with the NoK or participant over the phone. If discharged to another hospital, please see if you can call the team there, again to get as much information as possible.

Baseline Data:

Q: How do we know what stroke syndrome the participant has?
A: The deficits of each syndrome are explained in the brackets of the answers (e.g.TACS, weakness and/or numbness + dysphasia and/or neglect + hemianopia). Please choose the most relevant to the participant.

Q: If a patient is unable to answer some of the EAT-10 questions, how do we proceed to randomisation?
A: You can click the 'M' symbol next to the question, and report as not done / not known.

Serious Adverse Event Reporting:

Q: If a participant passes away and we complete the discharge / death form, do we still need to report a Serious Adverse Event?
A: Yes, all fatal SAEs are recorded and must be reported up until day 90.

Q: If the PI has signed the SAE form on redcap, do we also need to get a wet ink signature from them, and upload the form to the secure vault?
A: No, if the PI has reviewed and signed the form on redcap there is no need to do this.

Blinding

Q: If a participant has a VFS / FEES just before the day 14 follow up, can the blinded SLT know the outcome of them?
A: Yes, an unblinded SLT should give the blinded SLT a handover of the results. Please refer to the blinding WPD for more advice on blinding.

Q: Do the cognition forms need to be completed by a blinded researcher?
A: Ideally yes, but if unable to please complete unblinded, and write a comment at the bottom of the CRF to state it was done unblinded. The DSRS and associated SLT scales must be completed by a blinded SLT and researcher.

Q: What do I do if I become unblinded?
A: If you become inadvertently unblinded, see if there is another blinded member of staff who can do the follow up. If not, you can record on the CRF that you became unblinded, and how this happened.

Best Practice Tips:

Best practice tip:
When consenting a participant, please ensure you inform them that if they are randomised to receive PES, that they will need their standard NG tube replacing with a Phagenyx catheter, and that this will need replacing again with a standard NG tube at day 13 (if they are still requiring feeding).

Best practice tip:
If unsure of the FOIS score when working out eligibility, please consult the trial manual which gives detailed advice on how to score minimum amount and consistent amount trials.

Best practice tip:
Attempt recruitment into PhEAST as early as possible, so that participants are not discharged or moved to another hospital before the 14 day follow up.

Best practice tip:
The SLT team and research team should work together to screen and identify any potential participants.

Best practice tip:
Get ward nurses and doctors involved in the trial, they can be trained up to administer the treatment which can help with weekend cover, and even help to identify potential participants!