Local Letterhead to be added

**Participant Recovered Capacity (re-consent) Information Sheet**

(Final version 4.0: 07/03/2023)

**IRAS Project ID: 306761**

Title of Study: **Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)**

Name of Chief Investigator: **Prof. Philip Bath**

Local Researcher(s): xxxxxxxxxxxxxxxxxxxxxxxx

 You are being invited to consider continuing to take part in our research study. During your recent admission to hospital you were unable to give consent for entry into this study. We therefore asked your legal representative (welfare attorney/welfare guardian/nearest relative) who gave consent on your behalf. This is permissible under the Adults with Incapacity Act (Scotland) 2000. However, you are now capable of making an informed decision about whether you wish to continue in the study or not.
Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

# What is the purpose of the study?

The purpose of this study is to find out whether a regular course of treatment of Pharyngeal Electrical Stimulation (PES), stimulation of nerves in the throat that may have been damaged by your stroke, can help recovery back to eating and drinking by mouth. In four previous studies of PES involving stroke patients, the treatment devices were found to be safe and good performance was achieved in over 200 patients with no device-related adverse events being observed. The PES treatment can therefore be described as “low risk”. The study will also look at cognition and whether this is affected when you have had a stroke.

# Why have I been invited?

You are being invited to take part because you have been diagnosed as suffering from ‘neurogenic dysphagia’. This is the medical term for swallowing difficulties that are caused by injury or diseases that affect the brain and nerves controlling swallowing. Swallowing problems can lead to chest infections and the need to stay in hospital longer and can significantly affect your quality of life.

As you may need to have or already have a nasogastric (in the nose) feeding tube due to your swallowing difficulties, you may be suitable to take part in this study.

We are inviting a total of 800 participants like you to take part in this study, which will take about 36 months in total to be completed.

# Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights nor the standard of care you are entitled to receive.

# What will happen to me if I take part?

Your doctor/care team will have carefully checked if you are able to take part. For this they will have checked your medical records and asked a series of questions related to your condition. Some conditions may make it unsafe for you to receive PES such as having a pacemaker, being pregnant or requiring continuous oxygen therapy. The team will have checked all of this and let your legal representative (welfare attorney/welfare guardian/nearest relative) know if it would be suitable for you to take part.

This is a randomised control trial, meaning that after agreeing to participate, some patients will be allocated to receive the PES-treatment in addition to standard management for swallowing difficulties (dysphagia) while others will still receive the standard care management but without PES.

The patient or their doctor can’t decide which they will receive and it will be determined at random by a computer. For those participants allocated to standard care without PES, the same data will be collected and the same follow up procedures will be carried out.

If you are randomised to receive the PES-treatment, you may need additional chest X-rays to confirm that the catheter / NG tube is in the right place.

‘Pharyngeal Electrical Stimulation’ (PES) treatment is delivered using a commercially available medical device attached to a nasogastric feeding tube (Phagenyx®, Phagenesis Ltd, Manchester UK). The device is referred to as an integrated catheter. The outer part is a sleeve that incorporates the electrodes to deliver the current; the inner core houses the actual nasogastric feeding tube.



The treatment will involve electrical stimulation of the integrated catheter at a level of stimulation that will be customised to each participant’s tolerance above a required threshold current. The treatment will be administered in one 10-minute session per day over a period of six days, only by PES-trained research staff (co-ordinators, nurses, speech and language therapists). To eliminate bias, they will not be involved in analysing the results. Treatment will be stopped if there is no further need for tube feeding.

Following the six days of PES treatment, a study researcher not involved in the treatment, will carry out a number of standard clinical stroke-related assessments. They will ask you a few questions and examine your swallow, speech, eyesight, cognition, head, arms and legs to determine how the stroke has affected you. With your permission, they will record details of your condition, your test results and medications on a clinical log.

If you agree, we will send a letter to your GP informing them of your participation in the trial. We will also ask your permission to contact your GP or consult the NHS Information Centre to check on your health condition at three months, six months and 12 months after your stroke and to confirm your contact details.

A member of the research team will then contact you at Day 14,3 months, 6 months and twelve months after the treatment to carry out a repeat of the clinical assessments by questionnaire (via phone/email/post). This will take about 45 minutes to 1 hour of your time.

# Expenses and payments

Participants will not be paid to participate in the study.

# What are the possible disadvantages and risks of taking part?

In general, all procedures in this study are well tolerated by people. Although the PES-treatment is “low risk”, it is not impossible that an unanticipated risk may occur during the clinical study, but the chances of this happening are small and we have taken steps to make sure it is as safe as possible for you to take part. We will watch everyone in the study for any side effects and keep a special close watch on any health event. Specifically, the risks and unwanted events that can come about, are listed as follows;

1. *Insertion of nasogastric tubes into the throat is part of standard dysphagia care:* The insertion of the treatment tubes through the nose can cause mild but temporary irritation of the nose or throat. Experienced staff will carry out this procedure to minimise the discomfort. There has been no incidence of harmful complications caused by the insertion of such tubes in previous studies.
2. *Electrical stimulation of the throat:* The electrical stimulation can sometimes cause a moderate warm sensation at the back of the throat but this sensation is not painful.
3. *Chest X-*Ray: As part of the study you may receive up to 3 chest X-rays, some of which you would not have had if you did not take part. X-rays are a form of ionising radiation and are used to created images of your body. The risk of exposure to radiation is that you may develop cancer some years in the future. 1 in 2 people in the UK will develop cancer at some point in their lifetime. Taking part in the study will increase the chance of this happening to you by only a very small amount.

# What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help our understanding of how other patients with swallowing difficulties may be helped. Your swallowing function may improve after the study treatment (this is only for patients who are randomised to receive the treatment). If we observe that your swallowing has improved during the study, we will discuss this with their medical care team.

# What happens when the research study stops?

We would like to follow your progress at 3 months and 1 year. When all participants have been followed up, the trial results will be analysed and published in a medical journal. We will offer to send you a copy of the results.

# What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers’ contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting [please provide the contact details of PALS for the hospital/]

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

# Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you and your medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password-protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name, address and CHI number removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Where possible information about you which leaves the hospital will have your name, address and CHI number removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name, date of birth and CHI number. We will also need this information if we need to follow up your medical records as part of the research, where we may need to ask the Government services that hold medical information about you (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. We ask for your permission to do this and by signing the consent form you agree to the above.

Your contact information will be kept by the University of Nottingham for 12 months after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

# What will happen if I don’t want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. You will continue to receive the best guideline-based treatment. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

# Involvement of the General Practitioner/Family doctor (GP)

If you agree, we will send a letter to your GP informing them of your participation in the trial. We also ask your permission to contact your GP or check with the NHS Information Centre to check on your condition 3 months, 6 months and 1 year after your stroke and to confirm your contact details.

# What will happen to the results of the research study?

When all participants have been followed up, it is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research results have shown. We will present the findings at national and international conferences: the UK Stroke Forum; European Stroke Organisation Conference; International Stroke Conference; World Stroke Conference.

The results will contribute to the National Institute for Health and Care Excellence (NICE) assessment of this technology. They may be used to apply to the necessary authorities to make the intervention widely available, if shown to be beneficial.

At the end of the trial, the Patient-Public Involvement representative will be supported in disseminating the results and participant and relative-facing materials will be published on the trial website.

Participants will not be identified in any report/publication.

# Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by National Institute for Health Research (NIHR), the research arm of the NHS. The devices are being supplied by Phagenesis Limited (Manchester, U.K, the manufacturer of the PES-treatment. None of the research team members receive any payment beyond their normal salary for conducting the study.

# Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect participant’s interests. This study has been reviewed and given favourable opinion by Scotland A Research Ethics Committee.

# Further information and contact details

We are happy to answer any questions you may have relating to this study. Please ask the doctors or nurses on the ward, or the local principal investigator for further information.

Thank you very much for taking the time to read this leaflet.

**The member of the research team who gave you this information:**

Name:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_[insert details]

**Local principal Investigator:**

Name:

Address:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_ [insert details]

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