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Electrical stimulation of the throat for swallowing difficulties after stroke

Submission date 30/09/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/10/2021	**Overall study status** Ongoing	
Last Edited 23/07/2025	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Acute stroke is common and complicated by dysphagia (swallowing problems) in over 50% of patients, many of whom remain dysphagic a year later. Post-stroke dysphagia (PSD) is an independent predictor of poor outcome and can lead to aspiration of material into the lungs, pneumonia, malnutrition and death. Patients often need feeding through a tube, have a prolonged hospital stay, and end up in long-term institutional care. PSD negatively impacts quality of life and its care is expensive and may be a tipping point for admission to residential care. Pharyngeal electrical stimulation (PES) is electrical stimulation of certain areas of the throat that stimulates the areas of the brain involved in swallowing. This study aims to find out whether PES is safe and effective at improving post-stroke dysphagia.

Who can participate?
Hospitalised adults (aged 18 years and over) with recent stroke (within 4-31 days) and dysphagia

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. The intervention group receives PES on days 1-6 using a commercial catheter (tube) with an integral feeding tube. PES involves six daily 10 minute treatments. The control group will receive no PES catheter/stimulation on top of best guideline-based dysphagia management. A standard tube will be used for feeding as necessary.

What are the possible benefits and risks of participating?
The PES system is a non-significant risk device and its safety is shown by evidence from multiple studies over a period of 15 years. There are no characteristic device or treatment specific effects that are considered to be serious adverse events.

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
July 2021 to July 2025

Who is funding the study?
University of Nottingham (UK)

Who is the main contact?
Philip Bath
Philip.bath@nottingham.ac.uk

Study website
https://stroke.nottingham.ac.uk/pheast/

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304658

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 304658, NIHR132016, CPMS 50913

Study information

Scientific Title
Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

Acronym
PhEAST

Study objectives
To assess whether pharyngeal electrical stimulation (PES) is safe and effective at improving post-stroke dysphagia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2022, East of England - Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048227; essex.rec@hra.nhs.uk), ref: 21/EE/0252

Study design
International prospective randomized open-label blinded-endpoint (PROBE) parallel-group superiority Phase IV effectiveness trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Post-stroke dysphagia

Interventions
Current intervention as of 14/11/2023:
Randomised will be 1:1 with stratification on country and minimisation on age, sex, dysphagia severity rating scale (DSRS), impairment (National Institutes of Health stroke scale [NIHSS]), stroke type (ischaemic/haemorrhagic), circulation (anterior/posterior), time to randomisation; with 10% simple randomisation.

The intervention group will undergo PES administered for 6, ideally consecutive, days using a commercial catheter with an integral feeding tube. PES involves six daily 10 minute treatments at 5 Hz; threshold and tolerability currents will be assessed and the treatment current set at threshold + 0.75 x (tolerability - threshold) with the current generated by a base station. Dosing levels will be monitored, and sites informed if the stimulation current is too low, i.e. <20 mA; sites will be re-trained on the importance of delivering adequate current, if necessary. The catheter will be replaced once only if pulled out before three treatments have been administered. Treatment will be administered by PES-trained research coordinators, nurses or speech and language therapists (SLTs) who are not involved in outcome data collection.

The control group will receive no PES catheter/stimulation on top of best guideline-based dysphagia management. A standard NGT will be used for feeding as necessary.

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Randomised will be 1:1 with stratification on country and minimisation on age, sex, dysphagia severity rating scale (DSRS), impairment (National Institutes of Health stroke scale [NIHSS]), stroke type (ischaemic/haemorrhagic), circulation (anterior/posterior), time to randomisation; with 10% simple randomisation.

The intervention group will undergo PES administered on days 1-6 using a commercial catheter with an integral feeding tube. PES involves six daily 10 minute treatments at 5 Hz; threshold and tolerability currents will be assessed and the treatment current set at threshold + 0.75 x (tolerability - threshold) with the current generated by a base station. Dosing levels will be monitored, and sites informed if the stimulation current is too low, i.e. <20 mA; sites will be re-trained on the importance of delivering adequate current, if necessary. The catheter will be replaced once only if pulled out before three treatments have been administered. Treatment will be administered by PES-trained research coordinators, nurses or speech and language therapists (SLTs) who are not involved in outcome data collection.

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Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Phagenyx® (Phagenesis Ltd, Manchester, UK)

Primary outcome measure
Current primary outcome measure as of 14/11/2023:
Dysphagia assessed using the Dysphagia Severity Rating Scale (DSRS), based on bedside clinical assessment/management conducted at days 14 (-1/+3). Outcome assessment will be assessed by DSRS/Functional Oral Intake Scale (FOIS)-trained research coordinators, nurses or SLTs who are not involved in treatment.

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Previous primary outcome measure:
Dysphagia assessed using the Dysphagia Severity Rating Scale (DSRS), based on bedside clinical assessment/management conducted at days 14±1. Outcome assessment will be assessed by DSRS/Functional Oral Intake Scale (FOIS)-trained research coordinators, nurses or SLTs who are not involved in treatment.

Secondary outcome measures
Current secondary outcome measures as of 14/11/2023:
Measured on Day 14 -1/+3 (day 13-17):
1. Dysphagia assessed using the Functional Oral Intake Scale (FOIS), Feeding Status Score (FSS), and Eating Assessment Tool (EAT-10) on bedside clinical assessment
2. Diagnosis of pneumonia or infection assessed using medical notes
3. Weight measured on bedside assessment
4. NG tube/PEG in situ
5. Quality of life assessed using EQ-VAS/EQ5D5L and Barthel Index (BI) on bedside clinical assessment
6. Level of consciousness using the Glasgow Coma Scale (GCS)
7. Cognition assessments (MoCA, TICS, MMSE, semantic verbal fluency, phonemic verbal fluency, IQCODE)
8. Penetration Aspiration Score (PAS)

Measured on Day 90, Day 180 and Day 365 - all data collected via telephone assessment:
1. Dysphagia assessed using DSRS, FOIS, EAT-10
2. Feeding status assessed using FSS
3. Home-time measured in number of days participant has spent at home since stroke
4. Dependency assessed using modified Rankin Scale (mRS)
5. Disability assessed using Barthel Index (BI)
6. Quality of life assessed using EQ5D5L/EQVAS
7. Cognition assessed using Telephone interview for Cognitive Status (TICS)
8. Mood assessed using Zung depression scale
9. Disposition - where the participant has been discharged to - home, home with relatives, care home, residential home, nursing home, rehab unit

Measured on Day 365:
1. All-cause mortality - data collected from GP to establish whether participant has died

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Previous secondary outcome measures:
Measured on Day 7:
1. Stimulation threshold assessed on bedside assessment

2. Tolerability of stimulation assessed on bedside assessment
3. Record of current used as recorded in medical notes
4. Number of catheters used as recorded in medical notes

Measured on Day 14:
1. Dysphagia assessed using the Dysphagia Severity Rating Scale (DSRS), Functional Oral Intake Scale (FOIS), Eating Assessment Tool (EAT-10) on bedside clinical assessment
2. Feeding status assessed using FSS on bedside clinical assessment
3. Diagnosis of pneumonia or infection assessed using medical notes
4. Weight measured on bedside assessment
5. NG tube/PEG in situ/feeding status recorded using FSS from medical notes
6. Quality of life assessed using EQ-VAS/EQ5D5L on bedside clinical assessment
7. Discharge/death, data collected from the medical notes on discharge
8. Length of stay measured in number of days from admission to discharge
9. Swallowing therapy contact time measured in minutes spent with participant
10. Time to removal of NG tube/PEG - length of time participant has NG/PEG in situ measured in days
11. ICU admission measured in number of days spent in ITU
12. Discharged with PEG - answer yes/no if participant discharged with PEG
13. Disposition - where the participant has been discharged to - home, home with relatives, care home, residential home, nursing home, rehab unit

Measured on Day 90 - all data collected via telephone assessment:
1. Dysphagia assessed using DSRS, FOIS, EAT-10
2. Feeding status assessed using FSS
3. Home-time measured in number of days participant has spent at home since stroke
4. Dependency assessed using modified Rankin Scale (mRS)
5. Disability assessed using Barthel Index (BI)
6. Quality of life assessed using (EQ5D5L/EQVAS)
7. Cognition assessed using Telephone interview for Cognitive Status (TICS)
8. Mood assessed using Zung depression scale
9. Disposition - where the participant has been discharged to - home, home with relatives, care home, residential home, nursing home, rehab unit

Measured on Day 365:
1. All-cause mortality - data collected from GP to establish whether participant has died

Overall study start date
29/07/2021

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/11/2023:
1. Hospitalised adults (age ≥18 years)
2. Recent (4-31 days) ischaemic or haemorrhagic anterior or posterior circulation stroke (as diagnosed clinico-radiologically) at a comprehensive or primary care stroke centre
3. Clinical dysphagia defined as a functional oral intake scale score of 1 (nothing by mouth,

feeding by nasogastric tube [NGT]/percutaneous endoscopic gastrostomy [PEG] tube), 2 (tube dependent with minimal attempts of food or liquids) or 3 (tube dependent with consistent oral intake of food or liquids)
4. NIHSS item 1a score of 0, 1 or 2 (where the patient requires repeated stimulation to arouse)

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Previous inclusion criteria:
1. Hospitalised adults (age ≥18 years)
2. Recent (4-31 days) ischaemic or haemorrhagic anterior or posterior circulation stroke (as diagnosed clinico-radiologically) at a comprehensive or primary care stroke centre
3. Clinical dysphagia defined as a functional oral intake scale score of 1 (nothing by mouth, feeding by nasogastric tube [NGT]/percutaneous endoscopic gastrostomy [PEG] tube) or 2 (tube dependent with minimal attempts of food or liquids)

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
800

Key exclusion criteria
Current exclusion criteria as of 14/11/2023:
1. Non-stroke dysphagia, e.g. due to traumatic brain haemorrhage, subarachnoid haemorrhage, brain tumour, Parkinson's disease, multiple sclerosis, severe dementia, head or neck cancer
2. Pre-stroke dysphagia or dependency (modified Rankin scale, mRS 4/5)
3. NIHSS item 1a score of 2 (where the patient only responds to pain) or NIHSS item 1a score of 3
4. Ongoing or anticipated ventilation/intubation/tracheostomy
5. Ongoing treatment of dysphagia with other forms of electrical / magnetic stimulation e.g. NMES, TCDS, rTMS
6. Malignant middle cerebral artery syndrome (although this typically presents before 4 days)
7. Pacemaker, cochlear implant or implantable cardioverter-defibrillator
8. Need for >35% of oxygen
9. Patient expected to be repatriated to a separate organisation
10. Patient expected to be rehabilitated at a separate organisation
11. Patient not likely to be in the treating hospital for at least 14 days
12. Two or more NGT tubes pulled out unless nasal bridle in place
13. Investigator feels patient will not tolerate PES catheter
14. Expected to be discharged or transferred to a site not running the trial during the PES treatment period

15. Pregnancy if known at time of enrolment
16. Participating in another randomised controlled treatment trial for post-stroke dysphagia
17. Palliative care

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Previous exclusion criteria:
1. Non-stroke dysphagia, e.g., due to traumatic brain haemorrhage, subarachnoid haemorrhage, brain tumour, Parkinson's disease, multiple sclerosis, severe dementia, head or neck cancer
2. Pre-stroke dysphagia or dependency (modified Rankin scale [mRS] 4/5)
3. Ongoing or anticipated ventilation/intubation/tracheostomy or use of electrical or magnetic stimulation
4. Malignant middle cerebral artery syndrome
5. Pregnant
6. Pacemaker
7. Need for >2 litres of oxygen
8. Two or more NGT pulled out unless nasal bridle in place
9. Investigator feels the patient will not tolerate PES catheter

Date of first enrolment
30/05/2022

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Austria

Denmark

England

Germany

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road

Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Royal Victoria Hospital
274 Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
The Queen Elizabeth Hospital
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Royal London Hospital
Whitechapel Road
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
St George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Queens Medical Centre
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust

Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Warrington Hospital (site)
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
Royal Bournemouth General Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Fairfield General Hospital
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Study participating centre
King's Mill Hospital
Mansfield Road
Mansfield
United Kingdom
NG17 4JL

Study participating centre
University Hospital Llandough
Penlan Road
Llandough
Penarth
United Kingdom
CF64 2XX

Study participating centre
Dorset County Hospital
Dorset County Hospital
Williams Avenue
Dorchester
United Kingdom
DT1 2JY

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Nottingham

Sponsor details
Room East Atrium Jubilee Conference centre
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United Kingdom

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+44 (0)115 8467906
bb-sponsor@exmail.nottingham.ac.uk

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Phagenesis Ltd

Results and Publications

Publication and dissemination plan
1. Ongoing trial presentations at the UK Stroke Forum, European Stroke Organisation Conference, International Stroke Conference and World Stroke Conference
2. Protocol, statistical analysis plan and baseline characteristic publications in open-access journals (e.g. International Journal of Stroke, European Stroke Journal)

3. Primary results: oral presentation at a large international stroke conference times as per one of the above conferences. Open access publication in high impact journal to ensure maximum impact and rapid dissemination
4. Publication in HTA monograph
5. Secondary/tertiary/post hoc analyses: in appropriate journals (e.g. Stroke)
6. Subsequent presentations to inform UK, European and international guidelines
7. Provide evidence for NICE single technology appraisal (STA) assessment and guidance
8. Data sharing with the VISTA Stroke archive

Intention to publish date
30/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from PhEAST@nottingham.ac.uk addressed to the Trial Manager.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	02/12/2021	15/03/2022	No	No
HRA research summary			28/06/2023	No	No