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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 22/07/2026	**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
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Contact information

Type(s)
Scientific

Contact name
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Public

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Additional identifiers

Integrated Research Application System (IRAS)
304658

Central Portfolio Management System (CPMS)
50913

National Institute for Health and Care Research (NIHR)
132016

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

Primary study design
Interventional

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

Study type(s)
Treatment

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.

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.

Intervention Type
Device

Phase
Phase IV

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

Primary outcome(s)
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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

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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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
United Kingdom

England

Northern Ireland

Scotland

Wales

Austria

Denmark

Germany

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
Scotland
AB25 2ZN

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

Study participating centre
Royal Victoria Hospital
274 Grosvenor Road

Belfast
Northern Ireland
BT12 6BA

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

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

Study participating centre
Royal London Hospital
Whitechapel Road
Whitechapel
London
England
E1 1BB

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

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

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

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

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
Hazel Grove
Stockport
England
SK2 7JE

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

Study participating centre

Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

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

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

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

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

Study participating centre
King's Mill Hospital
Mansfield Road

Mansfield
England
NG17 4JL

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

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

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

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

Study participating centre
West Suffolk Hospital
Hardwick Lane

Bury St. Edmunds
England
IP33 2QZ

Study participating centre
Leighton Hospital
Leighton
Crewe
England
CW1 4QJ

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
DD1 9SY

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Phagenesis Ltd

Results and Publications

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 article		21/07/2026	22/07/2026	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	02/12/2021	15/03/2022	No	No
Study website		11/11/2025	11/11/2025	No	Yes