ISRCTN25681641 https://doi.org/10.1186/ISRCTN25681641

Swallowing treatment using electrical pharyngeal stimulation: a treatment of the throat for swallowing problems after stroke

Submission date
19/04/2012

Recruitment status
No longer recruiting

Registration date
19/07/2012

Overall study status
Completed

Last Edited
12/05/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Swallowing food and drink is part of our daily life and something that we do automatically. Sometimes people who suffer a stroke will have difficulties with swallowing which complicates their recovery. Food and drink may go down the wrong way and end up in the lungs, and this can cause chest infections. Patients with swallowing problems may be advised by the medical team to be nil by mouth or to only consume drinks that are thickened and food that is blended. Such advice is intended to help patients swallow more easily and safely in an attempt to reduce the risk of developing a chest infection. However, current methods of treating swallowing problems after a stroke are often not effective as some patients end up needing long-term feeding via a tube inserted into the stomach. This study aims to find out if electrical stimulation of the brain through stimulating nerves in the throat using a specially made tube (catheter) can speed up the recovery of safe swallowing in stroke patients.

Who can participate?
Patients aged 18 or older admitted to one of the participating hospitals following a stroke and diagnosed with dysphagia (swallowing problems).

What does the study involve?
Participants have a thin tube placed into the back of their throat at their bedside and are randomly allocated to receive either real (active) or sham (placebo) electrical pharyngeal stimulation treatment for three days. Swallowing is measured using a special X-ray examination called a Videofluoroscopy. This examination allows the amount of liquid entering the lungs to be assessed. At 2 and 12 weeks after the treatment has finished, a repeat swallow X-ray and a bedside assessment are carried out to look for any improvements in swallowing function. The research treatment is an add on to the standard clinical care that patients continue to receive on the ward.

What are the possible benefits and risks of participating?
Patients allocated to placebo treatment may not get any benefit. Patients in the active treatment group may experience a reduction in harmful swallows and may be more likely to

return to normal eating. The insertion of the stimulation tube through the nose can produce mild but temporary irritation of the nose or throat. Videofluoroscopy involves exposure to a low dose of radiation.

Where is the study run from?
The research trial will only take place in the participating hospitals.

When is the study starting and how long is it expected to run for?
April 2012 to December 2012

Who is funding the study?
Phagenesis Ltd (UK)

Who is the main contact?
Mrs Joanna Love
jo.love@phagenesis.com

Contact information

Type(s)
Scientific

Contact name
Mrs Joanna Love

Contact details
Phagenesis Ltd
Enterprise House
Pencroft Way
Manchester Science Park
Manchester
United Kingdom
M15 6SE
+44 (0)161 820 4525
jo.love@phagenesis.com

Additional identifiers

Protocol serial number
AHE01

Study information

Scientific Title
A multi-centre, double blind, randomised controlled clinical investigation to validate the EPS1 device as a treatment for stroke-induced dysphagia: a study of Swallowing Treatment using Electrical Pharyngeal Stimulation (STEPS study)

Acronym
STEPS

Study objectives
The Electrical Pharyngeal Stimulation 1 (EPS1) device improves swallowing function and reduces dysphagia-associated complications in stroke dysphagic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Essex, 06/02/2012, ref: 12EE/0005

Primary study design
Interventional

Study design
Multi-centre prospective randomised controlled two-arm double-blind clinical study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with dysphagia following acute anterior cerebral circulation or brainstem stroke

Interventions
Subjects are randomised to receive either real or sham pharyngeal electrical stimulation at low frequency. The intensity of the electrical stimulation is determined following the calculation of suitable sensory threshold, tailored to the individual participants. Subjects receive the intervention 3 times in a week, within a few days following index videofluoroscopy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Change in mean penetration-aspiration scores (PAS) on videofluoroscopy (VFS) post-treatment between (real and sham) treatment groups.

Key secondary outcome(s)
The secondary endpoints of this clinical investigation are (all will be compared to the placebo group excl. ease of use):
1. Incidence of all of adverse events
2. Change in Penetration-aspiration scores at 12-week assessment
3. Change in SALT management plan
4. Change in Dysphagia Severity Rating Scale (DSRS) at 2-week, and 12-week assessments
5. Change in NIHSS at 2, and 12-week assessments (see appendix F)
6. Change in mRS and BI at 2, 6 and 12-week assessments (see appendix D&E)
7. Frequency of chest infection up to discharge or 12-week follow up (whichever is sooner)
8. Time from randomisation to death (within 12-week follow-up)
9. Time from randomisation to removal of NG or PEG tube in relevant sub-stratum
10. Feeding status as 2, 6 and 12 weeks
11. Weight at 2 and 12 week assessments
12. BMI at 2 and 12 week assessments

13. Mid arm circumference at 2 and 12 weeks
14. Albumin at 2 and 12 week assessment
15. Discharge destination
16. Ease of use of the device by way of questionnaire to HCPs delivering (real or sham) treatment.
17. Quality of Life by means of EQ5D
18. To evaluate relationship between personality type and functional recovery

Completion date
23/12/2012

Eligibility

Key inclusion criteria
The target population is patients with dysphagia following acute anterior cerebral circulation or brainstem stroke that meet all the inclusion and exclusion criteria and are considered eligible to be entered into this clinical investigation.

Screening:
1. Subject is over 18 years of age
2. Subject is suspected of having dysphagia
3. Subject is able to comply with videofluoroscopy protocol
4. Subject diagnosed with stroke
5. Subject has no previous history of dysphagia
6. Subjects who are able to give voluntary, written informed consent to participate in the clinical investigation and from whom consent has been obtained/ or a consultee has consented on the subjects behalf in line with nationally agreed guidelines concerning adults unable to consent for themselves.
7. Subject is not currently participating in any other interventional clinical study
8. Subject is able to comply with clinical investigation plan requirements
9. Subject scores 0 or 1 on question 1a of the National Institute of Health Stroke Scale

Randomisation:
Subject has confirmed dysphagia (penetration-aspiration scores (PAS) of 3 or more during the videofluoroscopy (VFS) screening protocol)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subject stroke event was more than 42 days ago
2. Subject is pregnant or a nursing mother
3. Subject, in the opinion of the investigator, has advanced dementia
4. Subject fitted with a pacemaker or implantable cardiac defibrillator
5. Subject has unstable cardiopulmonary status
6. Subject has distorted oropharyngeal anatomy (e.g., pharyngeal pouch)
7. Subject is dysphagic from conditions other than stroke
8. Subject has been diagnosed with a progressive neurological disorder, such as Parkinsons, Multiple Sclerosis
9. Subject has a chronic medical condition that compromises cardiac or respiratory status (e.g. severe emphysema or heart failure that may render the insertion of the throat unsafe)
10. Subject is receiving continuous oxygen treatment or the equipment for this is in place

Date of first enrolment
05/04/2012

Date of final enrolment
23/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Phagenesis Ltd
Manchester
United Kingdom
M15 6SE

Sponsor information

Organisation
Phagenesis Ltd (UK)

ROR
https://ror.org/04a6evj08

Funder(s)

Funder type

Industry

Funder Name
Phagenesis Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2016		Yes	No