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A European registry to observe the use of the Phagenyx devices for the treatment of patients with swallowing difficulties.

Submission date
16/10/2014

Recruitment status
No longer recruiting

Registration date
28/10/2014

Overall study status
Completed

Last Edited
09/12/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Patients suffering from a variety of conditions such as stroke and Parkinsons disease often experience difficulty with swallowing. This is known as neurogenic dysphagia. A common problem caused by neurogenic dysphagia is that food or drinks may go down the wrong way and end up in the lungs. This can result in serious chest infections. This can make recovery from neurogenic dysphagia more complicated and often, alternative feeding methods are proposed as a therapy. To treat the symptoms of neurogenic dysphagia, patients are often given special training on swallowing techniques. However, this doesnt always work and some patients end up needing long-term feeding through a tube surgically placed in their stomach. Alternative treatments are available. One of these is called Pharyngeal Electrical Stimulation (PES), which is a simple and harmless technique for treating neurogenic dysphagia. The Phagenyx treatment is given through a tube inserted into the throat and is very similar to the type of tube used to temporarily feed people with swallowing difficulties. It can also be used to provide medicine and liquids. The treatment involves stimulating the nerves in the throat (pharynx) for 10 minutes each day for 3 days in a row to improve swallowing function. The intensity or level of the stimulation is adjusted on each day so that it is at the right level for the patient. Scientific research on shows that Phagenyx treatment can help improve swallowing. This previous research has mainly been performed in stroke patients, but other patients suffering from neurogenic dysphagia can also be treated by the device and may benefit from the treatment. Here, we will document the regular use of the Phagenyx treatment device in a registry.

Who can participate?
Patients aged at least 18 and have been identified as having neurogenic dysphagia due to a stroke, Parkinsons disease, Multiple Sclerosis or have been involved in an accident affecting the brain or are receiving artificial ventilation to help with breathing.

What does the study involve?
This study is to documenting the regular use of the Phagenyx treatment devices in the real world . It observes how the devices work and documents the potential benefit (or lack of benefit) of the treatment in patients suffering from a variety of conditions that have caused difficulties in

swallowing. It does not require any specific medical procedures to be done, other than those that are normally offered to patients with swallowing difficulties as standard treatment, which includes the Phagenyx treatment. As such, there are no experimental parts of this study. The intent is to only collect clinical data related to the Phagenyx treatment and its effects on neurogenic dysphagia.

What are the possible benefits and risks of participating?
In general, all procedures in this study are well tolerated by patients and are part of their routine care. Although the Phagenyx treatment is safe, it is not impossible that an unanticipated risk may occur during the study, but the chances of this happening are small and steps have been taken to make sure it is as safe as possible for patients to take part. All patients in the study will be carefully watched for any side effects. Specifically the risks and unwanted events that could occur can be listed as follows:
1. Insertion of tubes into the throat: 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 cases 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.

Where is the study run from?
Participating hospitals across Europe, the Middle East, Africa and Canada.

When is the study starting and how long is it expected to run for?
January 2015 to January 2017

Who is funding the study?
Phagenesis Limited (UK)

Who is the main contact?
Dr Jaak Minten
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AHE02

Study information

Scientific Title
A prospective, single-arm, observational clinical follow-up study on the application of PHAryngeal electrical stimulation for treatment of neurogenic Dysphagia: a European Registry (PHADER)

Acronym
PHADER

Study objectives
There is no specific hypothesis being tested in this registry-type of study: the purpose is to gather more evidence on the use and clinical outcomes of the Phagenyx products when used in daily practice (a real world environment) to treat swallowing difficulties caused by various conditions that affect the brain and its control of swallowing (known as 'neurogenic dysphagia').

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. All UK Sites: NRES Committee East of England - Cambridge Central, 22/04/2015, REC ref: 15/EE/0047
2. Austria:
2.1. Klagenfurt: Ethikkommision des Landes Kärten, 03/12/2015, Ref: A 16/14
2.2. Linz: Ethikkommision des Landes Oberösterreich, 27/08/2016, Ref: B-101-15
2.3. Innsbruck: Ethikkommision der Medizinischen Universtät Innsbruck, 30/11/2015, Ref: AN2014-0361 344/4.21 3508.8
3. Germany:
3.1. Munster (Lead ethics committee for Germany): Die Ethic-Kommission der Ärztekammer Westfalen-Lipp und der Westfälischen Wilhelms-Universität Münster, 14/07/2015, Ref: 2014-630-f-S
3.2. Hamburg (Local approval): Ethikkommision der Ärztekammer Hamburg, 11/12/2015, Ref: MC-367/15

Ethics submissions have also been made for two additional sites in Germany and Austria and are pending review.

Study design
Prospective, single-arm, observational clinical follow-up study.

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Neurogenic dysphagia

Interventions
We are conducting a post-market-release observational study of our device. All treatments delivered in this study are considered standard practice.

The Phagenyx treatment is given through a tube inserted into the throat and is very similar to the type of tube used to temporarily feed people with swallowing difficulty. It can also be used to provide medicine and liquids. The treatment involves stimulating the nerves in the throat (pharynx) for 10 minutes each day for 3 days in a row to improve swallowing function. The intensity or level of the stimulation is adjusted on each day so that it is at the right level for the patient.

Observations will be made at:
1. Screening
2. Baseline (before to first treatment)
3. Last day of treatment (Day 0)
4. Follow-up assessment 1: 24-72hrs (after day 0)
5. Follow-up assessment 2: Day 7 to day of discharge (<21 days) (after day 0)
6. Follow-up assessment 3: Day 60-120 (after day 0)

The total duration of follow-up will therefore be up to 120 days after the final day of treatment.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The primary objective is assessed by means of two standard functional scoring systems and one instrumental scoring system:

1. DSRS: Dysphagia Severity Rating Scale
2. FOIS: Functional Oral Intake Scale
3. PAS: Penetration Aspiration Scale

Secondary outcome measures
The secondary objectives are assessed by means of the following clinical data at one or more time points: baseline, at time intervals of 24-72 hrs, at pre-hospital discharge and at three months
1. Demographics described in terms of weight, age, sex, BMI, and assessment of distance between nostrils of the nose and the pharynx based on some external facial anatomical measures
2. Recording of the symptoms and underlying causes of dysphagia in treated patients
3. Assessment of the severity of swallowing using the Eating Assessment Tool (EAT-10) score
4. Assessment of the severity of secretion (Murray scale)
5. Measurement of the time and number of attempts to insert the stimulation catheter
6. Assessment of the ease of catheter positioning
7. Recording of subjective and personal appreciation of Phagenyx treatment prior and at the end of the study
8. Recording of the different Speech and Language Therapist-therapies in addition to the management plan at baseline
9. Measurement of the time period between Phagenyx treatment delivery and the dysphagia causal event
10. The outcome of DSRS and other standard scores related to the time of the day Phagenyx treatment is first delivered
11. Recording of the treatment optimisation parameters prior to every treatment delivery
12. Assessment of feeding status by means of the FOIS-score and the PEG-status
13. Recording of the type, purpose and duration of artificial ventilation
14. Recording of the timing of extubation or decannulation (in tracheostomy patients)
15. Assessment of the patients QoL using multiple questionnaires, such as the Barthel Index, the EURO-Qol-5D prior, and the Dysphagia Handicap Index
16. Recording of any device related Adverse Events and device deficiencies continuously during the observational study period
17. Recording of any health economics by assessment of the duration of the Intensive Care Unit-stay/hospitalisation/stay at different care giving units/discharge to home and of the total duration of mechanical ventilation/cannulation for a given purpose
18. Recording of the rehabilitation practice by the hospital discharge disposition at discharge from Intensive Care Unit, or from another care giving unit to home or another treatment unit /institute

Overall study start date
31/01/2015

Completion date
01/05/2018

Eligibility

Key inclusion criteria
Patients are eligible for study participation if they:
1. Are suspected to have oropharyngeal dysphagia with a Dysphagia Severity Ratings Scale (DSRS) score of 6 or higher

2. When eating independency would be jeopardised by partial or total paralysation of upper extremities and have a Functional Oral Intake Scale (FOIS) score equal to or lower than 5
3. When no oral food intake is possible and DSRS score is 12 and FOIS-score is 1 and have a Penetration-Aspiration Score (PAS) of 4 or higher
4. Have a well identified dysphagia causing neurological event such as, but not limited to, stroke or brain injury, potentially but not necessarily leading to the need of long-term mechanical ventilation or a tracheostomy
5. Are over 18 years old
6. Give themselves or have legal relatives/authorities representing themselves to give voluntary written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment
255

Key exclusion criteria
1. Have an undefined date of medical event causing the dysphagia
2. Suffer from non-neurogenic dysphagia (e.g. cancer)
3. Participate in any other study potentially influencing the outcome of the Phagenyx treatment, both medicinal or medical device product related
4. Receive or have received within one month prior to the intended Phagenyx treatment any other type of standard cranial or percutaneous electrical stimulation therapy to treat dysphagia
5. Have a cardiac pacemaker or a cardioverter defibrillator implanted unless the device can be switched off completely at the time of treatment delivery
6. Have experienced an oesophageal perforation, or have an oesophageal stricture or pouch;
7. Have an unstable cardiopulmonary status
8. Receive continuous oxygen treatment or have the equipment for such treatment permanently in place preventing the positioning of the Phagenyx Catheter (this does not exclude patients who are intubated or have a tracheostomy where an inflated balloon creates a firm barrier between the space where oxygen might be present (trachea/lungs) and the space where the electrical stimuli are delivered (oropharynx), or patients that can have the oxygen treatment temporarily stopped and equipment removed during Phagenyx treatment)
9. Are pregnant or nursing women
10. Require emergency treatment, preventing appropriate conduct of the subject informed consent process
11. Have a life expectancy less than the duration of the patients follow up period, i.e. less than three months

Date of first enrolment
01/03/2015

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
Austria

England

Germany

United Kingdom

Study participating centre
University of Nottingham
Division Of Stroke,
City Hospital Campus
Hucknall Road
Nottingham
United Kingdom
NG3 5LX

Study participating centre
University Hospital Münster (Universitätsklinikum Munster)
Klinik für Allegemeine Neurologie
Münster
Germany
48129

Study participating centre
Schön Kilinik Hamburg-Eilbek Hospital
Zentrum für Neurologie und Neurorehabilitation (Center of Neurology and Neurorehabilitation)
Dehnhaide 120
Hamburg
Germany
22081

Study participating centre

Schön Kilinik Munich-Schwabbing Hospital
Neurologsiche Rehabilitation und Frührehabilitation (Neurology Rehabilitation and Early Rehabilitation)
Parzivalplatz 4
München
Germany
80804

Study participating centre
Schön Kilinik Bad Aibling Hospital
Die Fachklinik für Neurologie und Alzheimer-TherapieNeurologie (The Clinic for Neurology and Alzheimer's Therapy)
Kolbermoorer Str. 72
Bad Aibling
Germany
83043

Study participating centre
Klinikum Klagenfurt Hospital
K:2102615 Anästh. ICU 2 (K)
Feschingstr. 11
Klagenfurt am Wörthersee
Klagenfurt
Austria
9020

Study participating centre
Hochzirl Hospital
Abteilung für neurologische
Zirl
Austria
6170

Study participating centre
AKh General Hospital Linz GmbH
Krankenhausstrasse 9
Linz
Austria
4020

Study participating centre

Royal Stoke University Hospital
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
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BH15 2JB

Study participating centre
Barmherzige Brüder Konventhospital Linz
Seilerstätte 2
Linz
Austria
4021

Study participating centre
Schön Klinik Bad Staffelstein Hospital
Am Kurpark 11
Bad Staffelstein
Germany
96231

Study participating centre
Alexianer Krefeld Hospital
Krankenhaus Maria-Hilf
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Sponsor information

Organisation

Phagenesis Limited (UK)

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Sponsor type
Industry

Website
http://www.Phagenesis.com

ROR
https://ror.org/04a6evj08

Funder(s)

Funder type
Industry

Funder Name
Phagenesis Limited (UK)

Results and Publications

Publication and dissemination plan
The study data is planned to be published (assuming the recruitment target is reached) in a peer reviewed international journal in 2018 after the study has completed.

We currently have no plans to make the participant-level data publicly available and free to use. The anonymised data will however be published in a peer reviewed international journal at the end of the study in 2018. A publication committee is established in the PHADER and will respond to any requests of this nature.

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	09/12/2020	Yes	No
HRA research summary			28/06/2023	No	No