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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
16/10/2014		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/10/2014	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
09/12/2020	Signs and Symptoms			

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 doesn't 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
Jaak.minten@fakkel-bvba.com

Contact information

Type(s)

Scientific

Contact name

Dr Jaak Minten

Contact details

FAKKEL-BVBA
Pellenstraat 7
Landen
Belgium
3400
+32 (0) 475923149
Jaak.minten@fakkel-bvba.com

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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 Unitstay/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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit



Sex

Αll

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

United Kingdom

England

Austria

Germany

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

Study participating centre

22081

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 United Kingdom 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 Diessemer Bruch 81 Krefeld Germany 47805

Sponsor information

Organisation

Phagenesis Limited (UK)

ROR

https://ror.org/04a6evj08

Funder(s)

Funder type

Industry

Funder Name

Phagenesis Limited (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes