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A study with patients who have swallowing difficulties and are artificially ventilated with a direct access tube to assess the benefit of using the Phagenyx device for early removal of the direct access tube

Submission date
06/02/2015

Recruitment status
No longer recruiting

Registration date
23/02/2015

Overall study status
Completed

Last Edited
03/09/2018

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] 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 including stroke or artificial ventilation typically have difficulty with swallowing, which is known as neurogenic dysphagia. A common problem caused by difficult swallowing is that food or drinks may go down the wrong way and end up in the lungs where they can cause serious chest infections. Patients who are artificially ventilated with a direct access tube, known as a tracheotomy tube, often experience swallowing difficulties and the tracheotomy tube can remain in place to prevent complications associated with swallowing difficulties. To treat the symptoms of difficult swallowing, patients are often given special training or swallowing techniques to use, but these are not always effective. There are alternative treatments. One of these is PES, which is a simple and harmless technique for treating difficult swallowing. PES treatment is delivered using a medical device (Phagenyx) that is commercially available and that can be used by patients' care teams on a routine basis at the bedside. 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 aim in this clinical study is to assess if PES treatment can help stroke patients with a tracheotomy tube in place have the tube removed earlier than in patients who do not receive the treatment at the same timepoint.

Who can participate?
Adults with swallowing difficulties after stroke

What does this study involve?
The study will involve observing how the devices work and documenting the outcome of the treatment. Apart from the PES treatment, no additional specific medical interventions are required in this study and patients will continue to receive standard care as recommended by their care team. Patients will be randomly allocated to either the early or the late treatment

group. All patients will receive the same standard PES treatment; however, those in the early group will receive the standard PES treatment immediately (0–24 hours) after randomisation. PES involves stimulating the nerves in the throat (pharynx) for 10 minutes each day for 3 days in a row to improve the swallowing function. The intensity or level of stimulation is adjusted on each day so that it is at the right level for the patient. An attempt to remove the tracheotomy tube will take place for patients in both the early and late treatment groups at the same timepoint after randomisation. If the tube cannot be removed successfully, patients in the early treatment group will receive a second standard PES treatment and patients in the late treatment group will be given their first standard PES treatment. After this standard PES treatment, there will be another attempt to remove the tracheotomy tube.

What are the possible benefits and risks of participating?
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. Possible risks are that 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) and electrical stimulation of the throat 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?
1. Universitätsklinikum Münster (Germany)
2. Allgemeines Krankenhaus der Stadt Linz (Austria)
3. Schön Klinik Hamburg Eilbek (Germany)
4. Uniklinik RWTH Aachen (Germany)
5. Klinikum Neukölln Berlin (Germany)
6. Isar Amper Klinikum Munich (Germany)
7. Klinikum Darmstadt (Germany)
8. Evangelisches Krankenhaus Bielefeld (Germany)
9. Universitätsklinikum Giessen (Germany)
10. MEDIAN Klinik Berlin-Kladow (Germany)
11. Ospedale San Gerardo Monza (Italy)
12. KABEG Klinikum Klagenfurt am Wörthersee (Austria)

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

Who is funding the study?
Phagenesis Limited (UK)

Who is the main contact?
Dr Jaak Minten

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
AHE03; EUDRMED Number: CIV-15-02-013145

Study information

Scientific Title
Benefit of PHAryngeal electrical STimulation for early de-cannulation in TRACheotomised stroke patients with neurogenic dysphagia : a prospective randomized single-blinded interventional study (PHAST TRAC study)

Acronym
PHAST TRAC

Study objectives
Current hypothesis as of 10/11/2015:
A significantly larger proportion of tracheotomised dysphagic patients after supratentorial stroke can be decannulated after a first period of pharyngeal electrical stimulation (PES) and following a standardised assessment scheme executed by the local blinded assessor /investigator at 24–72 hours after completion of treatment compared with control patients who only have standard therapy over the same period.

Previous hypothesis:
At least 25% more tracheotomised dysphagic patients after supratentorial stroke can be decannulated after a first period of pharyngeal electrical stimulation (PES) and following a standardised assessment scheme executed by the local blinded assessor/investigator at 24–72 hours after completion of treatment compared with control patients who only have standard therapy over the same period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Germany:
1. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 31/03/2015, ref: 2015-081-f-M
2. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 06/08/2015, ref: 2015-081-f-M,

3. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 02/11/2015, ref: 2015-081.f-M
4. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 28/12/2015, ref: 2015-081-f-M
5. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 12/01/2016, ref: 2015-081-f-M
6. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 09/05/2016, ref: 2015-081-f-M
7. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 09/01/2017, ref: 2015-081-f-M
8. Ethik Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultat der Westfälischen Wilhelms-Universisät, 23/03/2017, ref: 2015-081-f-M

Austria:
1. Ethikkommission der Medizinischen Universität Innsbruck, 16/10/2015, ref: AN2015-0119 349 /4.10
2. Ethikkommission der Medizinischen Universität Innsbruck, 14/03/2016, ref: B-95-15
3. Ethikkommission der Medizinischen Universität Innsbruck, 18/03/2016, ref: AN2015-0119 349 /4.10 359/5.11 (3784a)
4. Ethikkommission des Landes Oberösterreich, 29/04/2016. B-95-15
5. Ethikkommission der Landes Kärnten, 13/06/2016, ref: MZ 10/16

Italy:
Comitato Etico della Provincia Monza Brianza, 01/06/2016, ref: AHE-03 PHAST-TRAC

Study design
Randomised single-blind interventional study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients after supratentorial stroke with neurogenic dysphagia who need mechanical ventilation support initially but are weaned from this support and who are tracheotomised thereafter to reduce potential complications, but the tracheal tube cannot be removed due to ongoing swallowing problems and risks for penetration and aspiration of saliva

Interventions
1. CE-marked Phagenyx Base Station (EPS1) and Phagenyx catheter are commercially available for the treatment of neurogenic dysphagia and apply a standard electrical stimulation treatment at 5 Hz via the Phagenyx catheter, which is essentially a standard nasogastric feeding tube provided with built-in stimulation electrodes. The intensity of stimulation is optimised for each treatment by the Base Station software and operator input by setting the intensity at 75% of the tolerable limit above sensory threshold. The catheter houses an integrated circuit that allows the application of the 10 minute electrical stimulation therapy three times (i.e., during 3 consecutive days).
2. Removal of the tracheotomy tube will be attempted at the same timepoint after randomisation for patients in both the early and late PES treatment groups.

3. Patients in the early group will receive the standard PES treatment delivered by the Phagenyx device immediately (0–24 hours) after randomisation.
4. If the tube cannot be removed successfully, patients in the early treatment group will receive a second standard PES treatment and patients in the late treatment group will be given their first standard PES treatment. Removal of the tracheotomy tube will be attempted again after this standard PES treatment.

Intervention Type
Device

Primary outcome(s)
1. Proportion of patients in the early treatment group who can be decannulated* after the first exposure to standard PES treatment
2. Proportion of patients in the late treatment group who can be decannulated* at a similar timepoint without exposure to the standard PES treatment
Decannulation success measured at 3-5 days post Day 0 (randomisation) with Warnecke et al. 2013 decannulation protocol.

Added 27/07/2015:
*Cuff deflation is considered as decannulation

Key secondary outcome(s))
Current secondary outcome measures as of 10/11/2015:
1. Severity of dysphagia after PES treatment measured at Day 0 (randomisation), each decannulation attempt, every 48 hours for first 10 days, every 5 days after day 10 up to day 30 and at 3 months, measured with standard assessment scales (Dysphagia Severity Rating Scale [DSRS] and Functional Oral Intake Scale [FOIS]) and comparison with baseline
2. Success rates of decannulation in the late treatment group of the study after exposure to the standard PES treatment
3. Success rates of decannulation in the early treatment group of the study after a second exposure to the standard PES treatment
4. Treatment optimisation parameters (threshold, tolerance and intensity of the electrical stimulation)
5. Severity of the stroke measured using the standard NIHSS and modified Ranking Scale (mRS) at different time points after the PES treatment during the 30-day follow-up period and for mRS at the 3-month timepoint

Previous secondary outcome measures:
1. Severity of dysphagia after PES treatment measured at Day 0 (randomisation), each decannulation attempt, every 48 hours for first 10 days, every 5 days after day 10 up to day 30 and at 3 months, measured with standard assessment scales (Dysphagia Severity Rating Scale [DSRS] and Functional Oral Intake Scale [FOIS]) and comparison with baseline
2. Success rates of decannulation in the late treatment group of the study after exposure to the standard PES treatment
3. Success rates of decannulation in the early treatment group of the study after a second exposure to the standard PES treatment
4. Treatment optimisation parameters (threshold, tolerance and intensity of the electrical stimulation)
5. Severity of the stroke, measured with the standard National Institutes of Health Stroke Scale and modified Ranking Scale at Day 0 (randomisation), day 10 and every 5 days up to days 30, and at 3 months

Completion date
05/07/2017

Eligibility

Key inclusion criteria
1. Haemorrhagic or ischaemic stroke
2. Supratentorial
3. Mechanically ventilated for a minimum of 48 hours after the stroke event
4. Tracheotomised for any reason
5. Weaned from mechanical ventilation
6. Not taking sedatives for a minimum of 3 days
7. Ineligible for decannulation for a minimum of 10 days after the stroke event
8. Ineligible for decannulation for a minimum of 24 hours and a maximum of 72 hours after the first decannulation assessment
9. Cannot receive oral food (DSRS=12 and FOIS = 1)
10. Richmond Agitation and Sedation Scale > – 1
11. > 18 years old
12. Voluntary written informed consent provided by patients or their legal relatives/authorities

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 27/07/2015:
1. Undefined date of stroke causing the dysphagia (but not excluded stroke occurring during the night, for which the date will be the morning the stroke was observed)
2. Pre-existing dysphagia
3. Infratentorial stroke
4. Pre-existing neurogenic dysphagia or a disease linked to this symptom (e.g., Parkinson disorder)
5. Non-neurogenic dysphagia (e.g., cancer)
6. Neuromuscular disorders (e.g., myasthenia gravis or motor neurone disease)
7. Participating in any other study (of a medicine or medical device) that might affect the outcome of PES, and for which the patient signed a consent form
8. Receiving or have received within 1 month before the intended PES treatment any other type of standard cranial or percutaneous electrical stimulation therapy to treat dysphagia
9. Have a pacemaker or an implantable defibrillator

10. Have a nasal anatomical deformity, nasal airway obstruction, have had oesophageal surgery or any other circumstance where placement of a standard NG feeding tube would be deemed unsafe
11. Have a cardiac or respiratory condition that might render the insertion of the catheter into the throat unsafe
12. Receive oxygen therapy whilst the oxygen supply is in place or in operation
13. Pregnant or nursing women
14. Requiring emergency treatment that prevents the appropriate informed consent process
15. Life expectancy less than the duration of the patient's follow-up (i.e., < 3 months)

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1. Undefined date of stroke causing the dysphagia (but not excluded stroke occurring during the night, for which the date will be the morning the stroke was observed)
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4. Pre-existing neurogenic dysphagia or a disease linked to this symptom (e.g., Parkinson disorder)
5. Non-neurogenic dysphagia (e.g., cancer)
6. Neuromuscular disorders (e.g., myasthenia gravis or motor neurone disease)
7. Participating in any other study (of a medicine or medical device) that might affect the outcome of PES, and for which the patient signed a consent form
8. Receiving or have received within 1 month before the intended PES treatment any other type of standard cranial or percutaneous electrical stimulation therapy to treat dysphagia
9. Cardiac pacemaker or cardioverter defibrillator, unless device can be switched off completely at the time of treatment
10. Oesophageal perforation, oesophageal stricture or pouch
11. Unstable cardiopulmonary status
12. Severe pneumonia that cannot be stabilised by medication and prevents decannulation
13. Receiving continuous oxygen treatment or having equipment for such treatment permanently in place, preventing the positioning of the Phagenyx catheter (does not exclude patients who are intubated or have a tracheotomy in which 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 who can have the oxygen treatment temporarily stopped and equipment removed during PES treatment)
14. Pregnant or nursing women
15. Requiring emergency treatment that prevents the appropriate informed consent process
16. Life expectancy less than the duration of the patient's follow-up (i.e., < 3 months)

Date of first enrolment
01/04/2015

Date of final enrolment
09/05/2017

Locations

Countries of recruitment
Austria

Germany

Italy

Study participating centre
Universitätsklinikum Münster
Münster
Germany
48149

Study participating centre
Allgemeines Krankenhaus der Stadt Linz
Austria
-

Study participating centre
Schön Klinik Hamburg Eilbek
Germany
-

Study participating centre
Uniklinik RWTH Aachen
Germany
-

Study participating centre
Klinikum Neukölln Berlin
Germany
-

Study participating centre
Isar Amper Klinikum Munich
Germany
-

Study participating centre
Klinikum Darmstadt
Germany
-

Study participating centre
Evangelisches Krankenhaus Bielefeld
Germany
-

Study participating centre
Universitätsklinikum Giessen
Germany
-

Study participating centre
MEDIAN Klinik Berlin-Kladow
Germany
-

Study participating centre
Ospedale San Gerardo Monza
Italy
-

Study participating centre
KABEG Klinikum Klagenfurt am Wörthersee
Austria
-

Sponsor information

Organisation
Phagenesis Limited

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 summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2018		Yes	No
Protocol article	protocol	01/06/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes