# 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	<b>Recruitment status</b>	[X]	Prospect
	No longer recruiting	[X]	Protocol
<b>Registration date</b> 23/02/2015	<b>Overall study status</b>	[]	Statistica
	Completed	[X]	Results
Last Edited 03/09/2018	<b>Condition category</b> Nervous System Diseases		Individua

- ] Statistical analysis plan
- ] 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** Dr Satish Mistry

## **Contact details**

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

**Secondary identifying numbers** 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

Secondary study design Randomised parallel trial

Study setting(s) Hospital

**Study type(s)** Quality of life

# Participant information sheet

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

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 measure

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

# Secondary outcome measures

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

# Overall study start date

01/04/2015

# **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

# Age group

Adult

# Lower age limit

18 Years

**Sex** Both

### Target number of participants

It is expected that about 80 patients will be enrolled in the study, however sequential analysis is applied and due to possible variability in observations, the number might increase to above 126, which constitutes the 90th percentile of the possible expected required number of patients

### 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)

Previous exclusion criteria:

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

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**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

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**Study participating centre KABEG Klinikum Klagenfurt am Wörthersee** Austria

# Sponsor information

**Organisation** Phagenesis Limited

## Sponsor details

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### Sponsor type

Industry

Website 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

Results of the study will be published in peer-reviewed journals. A Scientific Committee, composed by the Coordinating Investigator, the Chief Scientific Officer, the Biostatitistician and a sponsor's representative, will establish a publication policy to allow appropriate identification and ranking of authors from the participating investigational sites, as well as to identify the content and optimal timing of each publication. Aside from the main publication, which will appear within one year after closure of the clinical trial in line with the ISO 14155, clinical data will be presented on international congresses.

### Intention to publish date

05/07/2018

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?
<u>Protocol article</u>	protocol	01/06/2017		Yes	No
Results article	results	01/10/2018		Yes	No