A Non-randomized Study to Evaluate the Safety and Performance of the Portaero Pneumostoma System in Patients with Severe Emphysema and Hyperinflation of the Lung

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The objective of this study is to evaluate the safety and device performance of the Portaero Pneumostoma System to create and maintain a transthoracic pneumostoma in patients with severe emphysema and hyperinflation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34355

Source
ToetsingOnline

Brief title
Portaero trial

Condition

- Respiratory disorders NEC

Synonym
COPD, Emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Portaero Inc.
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: Airway bypass, COPD, Emphysema, Pneumostoma

Outcome measures

Primary outcome

Study Outcomes

* Safety

The safety assessments include the incidence of complications and adverse

events.

* Performance

Primary:

Improvement is shown at 6 months when at least one of the following is

achieved:

* change in FEV1 of greater than or equal to 12% (FEV1 >=12%) from baseline;

* decrease in SGRQ (Total) of 4 points or more from baseline.

Secondary outcome

Changes in FVC, RV, RV/TLC, lung volume CT Scan, 6MWT, cycle ergometry, mMRC

dyspnea score, and EQ-5D.

Study description

Background summary

Currently, there is no non-invasive procedure that can adequately alleviate the

debilitating effects of severe emphysema. Self-care, medications, long-term oxygen therapy, and surgery are either insufficient or too invasive (e.g., lung transplant) for the compromised patient.
To fulfill the unmet needs, Portaero, Inc. has developed the Portaero Pneumostoma System consisting of the surgical Portaero Access Tube device and its accessory components to create a channel from the interior of the lung through the thoracic wall and exposing it to atmosphere, and the Portaero Disposable Tubes to maintain the channel after it has properly healed and formed. The goal is to expel trapped gas in the emphysematous lung. The potential benefits of the Portaero Pneumostoma System include an increase in exhaled airflow and gas exchange, and decrease in work of breathing, residual volume, and dyspnea with subsequent improvement in patient*s quality of life.

New information gathered from previous pilot work lead efforts to redesign the Portaero Access Tube and Portaero Disposable Tube. To bring the next generation Portaero devices to the Investigators, this protocol is developed to evaluate the redesigned Portaero Pneumostoma System. The new designs are anticipated to improve comfort and minimize device displacement observations.

Study objective

The objective of this study is to evaluate the safety and device performance of the Portaero Pneumostoma System to create and maintain a transthoracic pneumostoma in patients with severe emphysema and hyperinflation.

Study design

This is a prospective, non-randomized, multicenter study to evaluate the safety and device performance of the Portaero System for use in a unilateral transthoracic pneumostoma procedure.

Intervention

Pneumostoma Surgical Technique
The Portaero Access Tube is placed either percutaneously or through a small incision, 4-8 cm in length, on the chest wall of the target lung. In both insertion techniques, a chest drain is placed in the thoracic pleural space to assist re-inflation of the lung. The use of vacuum or underwater seal to manage the chest drain will be at the discretion of the surgeon.
A portion of the underlying rib at the access point can be resected to provide operating space if required.
A second portal of entry may also be created for endoscopic visualization of the pleural cavity and insertion of an intercostal catheter for post operative drainage of air from the pleural cavity.

Study burden and risks

SCREENING: Outpatient Clinic Visit, Blood, Lung function tests, chest X-ray, HRCT scan of the lungs, Echo of the heart
Included subjects will undergo a pulmonary rehabilitation program for approximately 6 weeks and then:

BASELINE: Outpatient clinic visit, lung function tests, 6-minute walk test, 2 x bicycle test

RECORDING: the patient will be admitted to the hospital for 1-2 week for the surgery under general anesthesia.

FOLLOW-UP: five Outpatient clinic visits, two pulmonary function test, two times 6 minutes walk test, 4 chest X-ray, an HRCT-scan of the lungs, two bicycle tests

The included patients will have to put large effort in the study, but is in balance with the expected outcome and very limited compared 'alternative' treatments like highly invasive surgery: Lung volume reduction surgery or Lung transplantation. All included patients have a severe limitation of their activities of daily living. With the development and validation of the use of the Pneumostomoa does it seem possible to give -at least temporarily- relieve of shortness of breath and improvement in expercise performance. Furthermore can this technique be used as a 'bridge' to lungtransplantation in future, or will be the only possible therapeutic tool available by then. The risks are not bigger than the risks any individual has for the investigations described.

The following list of potential risks associated with the transthoracic pneumostoma procedure are summarized below:
* Acute respiratory failure
* Infection (i.e., local pneumostoma infection)
* Anesthetic reaction
* Inflammation
* Bleed (i.e., hemorrhage, hemoptysis, local pneumostoma bleed)
* Pneumomediastinum
* Pneumothorax
* Bronchocutaneous fistula
* Respiratory infection
* COPD exacerbation
* Subcutaneous emphysema
* (Worsening of) Dyspnea
* Transient pain/discomfort at pneumostoma site
* Granulation tissue
* Death

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- HRCT consistent with severe emphysema grade >2/4
- FEV1 < 45% predicted
- Patient with hyperinflation defined as RV > 150% predicted, TLC > 100% predicted
- Arterial Bloodgas PaO2 > 45 mmHg and PaCO < 60 mmHg
- Stopped smoking and with a smoking history of > 20 pack years

Exclusion criteria

- History of recurrent respiratory infections
- Cardiovasculair pathology
- Inability to walk > 140 meters in 6 minutes

- Giant bullae (> 1/3 lung volume)
- Patient is taking > 10 mg prednisone (or similar steroid) daily
- Patient has evidence of other disease that may compromise survival (such as lung cancer)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2010
Enrollment:	7
Type:	Actual

Medical products/devices used

Generic name:	Pneumostoma Access Tube
Registration:	No

Ethics review

Approved WMO

Date:	27-08-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32842.042.10