A RandomizEd ControlLed Study of PnEumRx Endobronchial Coil System Versus Standard-of-Care Medical MAnagement in the Treatment of Subjects with Severe Emphysema (ELEVATE) A Postmarket Surveillance Study (PMS).

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

Summary

ID

NL-OMON46536

Source
ToetsingOnline

Brief title
ELEVATE

Condition

- Respiratory disorders NEC

Synonym
COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: PneumRx, Inc.
Source(s) of monetary or material Support: PneumRx

Intervention

Keyword: Bronchoscopy, COPD, Emphysema, Lung volume reduction

Outcome measures

Primary outcome

Safety: number and kind of (serious) adverse events

Co-Primary Effectiveness Endpoints:

* Percent change in FEV1 from baseline to 6 months and

* Change in SGRQ from baseline to 6 months

Secondary outcome

Secondary Effectiveness Endpoints:

** Responder rate at 6 months defined as percent of subjects that achieve two

or more of the following MCIDs;

Change from baseline in:

6MWT * 26 meters, SGRQ * -4 points, FEV1 * 10%, Decrease in RV < 350 ml

* *Change in Mean Expiratory Lobar Volume (LoVRexp) of the treated lobes from

Baseline to 6 months

* *Change in Vital Capacity (VC) as measured by plethysmography from Baseline

to 6 months

Other Effectiveness Endpoints:

** Changes in other Pulmonary Function measures (RV, RV/TLC, FEV1, FEV1/FVC)

* *Change in Exercise Capacity (6MWT)

* *Change at 6 months for CAT and EQ5D

* *Individual MCID responder rates at 6 months for 6MWT, SGRQ, and FEV1 as

defined above

* *Responder rate at 6 months defined as percent of subjects that achieve FEV1

* 12%

* *Responder rate at 6 months defined as percent of subjects that achieve SGRQ

* -8 points

Study description

Background summary

The PneumRx RePneu Lung Volume Reduction Coil (RePneu LVR-coil) is a bronchoscopic lung volume reduction treatment designed to compress the areas of lung parenchyma most damaged by emphysema. The LVRC treatment was found to be feasible, safe and effective in previous studies. Another aspect of the treatment which we to date do not fully understand is which group of patients benefit of the treatment and which group of patients do not, this knowing that the responder rate is already about 60%. The RENEW trial, a multicenter RCT identified various subgroups of patients with a better clinical response after the coil treatment. This trial will investigate the safety and efficacy of the coil treatment in this group op best responders to hopefully gain more insight on the best-responder profile of the treatment.

Study objective

The primary objective of the study is to prospectively confirm the safety and effectiveness profile of Coil treatment in consideration of the findings of previous Randomized Controlled Trials.
Secondary objectives are determination of responder rates to clinical endpoints and mean change in physiologic endpoints.

Study design

Prospective, multicenter, open label, randomized (2:1), controlled study comparing outcomes in subjects treated with the PneumRx Endobronchial Coil System (Coil) to a medically-managed control group. The medically-managed control group will be eligible to crossover after 6 months.

Intervention

The Coil System is a CE-Marked implantable device that is indicated for use in patients with homogeneous and/or heterogeneous severe emphysema to improve quality of life, lung function, and exercise capacity.
The Coil System consists of sterile Endobronchial Coils which come in 3 different sizes (100 mm, 125 mm, and 150mm) and a sterile, disposable, single-procedure Delivery System consisting of a Cartridge, Catheter, Guidewire and Forceps.
The Coil System is designed for bilateral treatment using a therapeutic bronchoscope with a 2.8 mm working channel and fluoroscopy for visualization beyond the bronchoscope.

Study burden and risks

The LVR Coil has been designed to be as safe as possible. It was shown that the risks associated with the LVRC system are largely attributable to the bronchoscopic procedure itself rather than to the device per se. Therefore, it appears that the LVRC device itself does not appreciably increase the risk of serious adverse events beyond the risk of undergoing a bronchoscopy procedure or simply having emphysema. Currently, this treatment is not commercially available in the Netherlands and study participants will have to visit the hospital multiple times. Previous studies have shown that the treatment has beneficial effect for the patient, however not all patients respond. Therefore, it is possible that a patient will not receive any benefits from the treatment.

Contacts

Public
PneumRx, Inc.

Burton Drive 4255
Santa Clara 95054 CA
US
Scientific
PneumRx, Inc.

Burton Drive 4255

Santa Clara 95054 CA
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Read, understood and signed the Informed Consent form
2. Meets indications for use per the IFU
3. Bilateral heterogeneous and/or homogeneous emphysema
4. 15% predicted * Post bronchodilator Forced Expiratory Volume in 1 second (FEV1) * 45% predicted
5. Post bronchodilator Residual Volume (RV) * 200% predicted
6. Post bronchodilator Total Lung Capacity (TLC) >100% predicted
7. Post bronchodilator RV/TLC > 55%
8. Dyspnea * 2 on modified Medical Research Council (mMRC) dyspnea scale despite optimal medical management
9. Receiving optimal drug therapy and medical management according to clinical practice.
10. Performing regular physical activity, at least 2 times per week 3
11. Stopped smoking as confirmed by carboxyhemoglobin (CoHB)
12. 100m * 6 minute walk distance (6MWD) * 450m
13. Deemed eligible per Eligibility Review Committee (ERC)

Exclusion criteria

1. Meets any of the contraindications listed in the IFU
2. Primary diagnosis of asthma
3. Two (2) or more COPD exacerbations in the prior year, or 1 or more COPD exacerbations in the prior 3 months with indication for hospitalization assessment, according to GOLD 2017 recommendations4.
4. Predominant small airways disease defined as significant bronchiectasis with sputum

production (> 2 tablespoons daily) or significant bronchial wall thickening per High Resolution Computed Tomography (HRCT)
5. Percent Low Attenuation Area (%LAA) < 20% in the most damaged lobe of either lung.
6. Computed Tomography (CT) Imaging consistent with active pulmonary infection, significant interstitial disease or pleural disease (predominant bulla > 8cm or 1/3 hemithorax), or severe bullous or predominant paraseptal emphysema pattern
7. Lung pathology of nodule not proven stable or benign
8. Radiographic confirmation of atelectasis or other scarring/fibrosis in areas of intended Coil implant 9. Use of more than 10 mg/day prednisolone or equivalent dosage of a different corticosteroid
10. Severe pulmonary hypertension (Right Ventricular Systolic Pressure (RVSP) > 50 mm Hg or other signs of Pulmonary Hypertension (PHT) with right ventricular dysfunction)
11. Severe hypercapnia (PaCO2 > 55 mmHg on room air) and/or severe hypoxemia (PaO2 < 45mm Hg on room air, High altitude criterion: PaO2 < 30 mm Hg)
12. Previous Lung Volume Reduction (LVR) surgery, lung transplantation, lobectomy, LVR devices or other device to treat COPD in either lung.
13. Diagnosed with alpha-1 antitrypsin deficiency
14. DLCO < 20 %
15. Significant, recent or unstable cardiac disease defined as severe heart failure (Left Ventricular Ejection Fraction (LVEF) < 45% despite optimal medical management), unstable cardiac arrhythmia or coronary artery disease (angina on activity), or ischemic event in the past 6 months.
16. Body Mass Index (BMI) > 30.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Bronchoscopic Lung Volume Reduction Coil treatment
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-03-2018
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
ClinicalTrials.gov	NCT03360396
CCMO	NL64150.042.18