The safety and feasibility of re-treating patients with severe emphysema with the RePneu LVRC system: a pilot study.

Published: 12-12-2013
Last updated: 22-04-2024

Primary Objective: To investigate the safety and feasibility of re-treating patients with COPD with the RePneu LVRC system.Secondary Objective: To investigate the effectiveness of re-treating patients with COPD with the RePneu LVRC system on lung...

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

Summary

ID

NL-OMON38678

Source
ToetsingOnline

Brief title
RECOIL study

Condition

- Respiratory disorders NEC

Synonym
COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bronchoscopy, COPD, emphysema, lung volume reduction

Outcome measures

Primary outcome

The safety objective of this study is to identify the potential number and type

of device-related and procedure-related adverse effects.

Secondary outcome

Lung function

- Change in RV, 6 months following treatment

- Change in RV/TLC ratio, 6 months following treatment

- Changes in FEV1 and FVC, 2 and 6 months following treatment

Quality of life

- Change in the SGRQ score, 2 and 6 months following treatment

- Change in the CCQ score, 2 and 6 months following treatment

Functional measures

- Change in the mMRC score, 2 and 6 months following treatment

- Change in the 6MWD, 2 and 6 months following treatment

Study description

Background summary

Current treatment of severe emphysema (COPD GOLD stages III-IV) generally is limited to palliative measures that include supplemental oxygen, bronchodilators, anti-inflammatory drugs and pulmonary rehabilitation. A small subset of patients with emphysema might benefit by lung volume reduction surgery, but this procedure is highly invasive and often results in high morbidity and mortality. A minimally invasive treatment with the potential to

improve pulmonary function and reduce dyspnea in patients with both heterogeneous and homogeneous emphysema would provide meaningful clinical benefit.

One example of a minimally invasive treatment is the PneumRx RePneu Lung Volume Reduction Coil (RePneu LVRC) system that is designed to compress the areas of lung parenchyma most damaged by emphysema. This device is deployed using a minimally invasive approach using a simple catheter-based delivery system through a fiber optic bronchoscope and requires no incision. And the combined data from 3 studies outside the Unites States investigating the LVRC system showed statistically significant improvements in pulmonary function, exercise capacity and quality of life at both 6-Months and 12-Months post treatment.

24 months post treatment the improved pulmonary function, quality of life and exercise capacity is decreasing. Retreating the patient with the LVR coil system in other parts of the lung could potentially lead to new improvements in lung function, dyspnea, exercise capacity and quality of life and may reduce the rate of decline.

Study objective

Primary Objective:
To investigate the safety and feasibility of re-treating patients with COPD with the RePneu LVRC system.

Secondary Objective:
To investigate the effectiveness of re-treating patients with COPD with the RePneu LVRC system on lung function, quality of life measures and functional measures.

Study design

Non randomized uncontrolled intervention study

Intervention

Patients will receive a lung volume reduction coil treatment by bronchoscopy.

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.

Patients will be included if they significantly improved in lung function, quality of life or exercise after the first treatment with the LVRC system. We expect that the second treatment with the LVRC will also be beneficial for the patients. However, it is possible that a patient will not receive any benefits from the treatment.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Treated with the RePneu LVRC system > 24 months ago.
2) Six months after the first bilateral treatment with the RePneu LVRC system the patient had a significant improvement above the established minimal important difference (MID) of 6-minute walk distance (6MWD: 26 meter)
or of forced expiratory volume in 1 second (FEV1: 100ml)

or of St. Georges Respiratory Questionnaire total score (SGRQ: 4 points).
3) Subject has marked dyspnea scoring >=2 on mMRC scale of 0-4.
4) Subject has stopped smoking for at least 6 months prior to entering the study.
5) Subject read, understood and signed the Informed Consent form.
6) Subject has completed a pulmonary rehabilitation program within 6 months prior to treatment and/or regularly performing maintenance respiratory rehabilitation if initial supervised therapy occurred more than 6 months prior to baseline testing.
7) Subject has received Influenza vaccinations consistent with local recommendations and/or policy.

Exclusion criteria

1) Subject has co-morbidities that may significantly reduce subject*s ability to improve exercise capacity (e.g., severe arthritis, planned knee surgery) or baseline limitation on 6MWT is not due to dyspnea.
2) Subject has severe gas exchange abnormalities as defined by:
PaCO2 >8.0 kPa;
PaO2 < 6.0 kPa (room air).
3) Subject has a history of recurrent clinically significant respiratory infections, defined as 3 hospitalizations for respiratory infection during the year prior to enrollment.
4) Subject has severe pulmonary hypertension defined by right ventricular systolic pressure >50 mm Hg via echocardiogram.
5) Subject has an inability to walk >140 meters in 6 minutes.
6) Subject has evidence of other severe disease (such as, but not limited to, lung cancer or renal failure), which in the judgment of the investigator may compromise survival of the subject for the duration of the study.
7) Subject is pregnant or lactating, or plans to become pregnant within the study timeframe.
8) Subject has an inability to tolerate bronchoscopy under moderate sedation or general anesthesia.
9) Subject has clinically significant bronchiectasis.
10) Subject has giant bullae >1/3 lung volume.
11) Subject has had previous LVR surgery, lung transplantation or lobectomy.
12) Subject has been involved in pulmonary drug or device studies within 30 days prior to this study.
13) Subject is taking >20 mg prednisone (or equivalent dose of a similar steroid) daily.
14) Subject requires high level chronic immunomodulatory therapy to treat a moderate to severe chronic inflammatory autoimmune disorder.
15) Subject is on an antiplatelet (such as Plavix) or anticoagulant therapy (such as heparin or Coumadin) which cannot be stopped for 7 days prior to procedure.
16) Subject has a sensitivity or allergy to Nickel.
17) Subject has a known sensitivity to drugs required to perform bronchoscopy.
18) Subject has any other disease, condition(s) or habit(s) that would interfere with completion of study and follow up assessments, would increase risks of bronchoscopy or assessments, or in the judgment of the investigator would potentially interfere.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2014
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2013
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	NL45374.042.13
Other	wordt nog aangemeld bij clinical trials.gov voor aanvang van de studie