Identifying REsponders and exploring mechanisms of ACTION of the endobronchial coil treatment for emphysema

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

Summary

ID

NL-OMON44603

Source
ToetsingOnline

Brief title
REACTION

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: PneumRx,unrestricted grant PneumRx GMBH

Intervention

Keyword: Bronchoscopy, COPD, Emphysema, Lung volume reduction

Outcome measures

Primary outcome

1) The main study endpoint is the change in physical activity between baseline

and 3 months follow-up after the second treatment.

Secondary outcome

2) To investigate the change between baseline and 3 months follow up after the

LVR-coil treatment in:

- patient reported outcomes of the treatment using a dedicated questionnaire

(PSK)

- dynamic lung hyperinflation (metronome paced)

- static lung volumes

- lung compliance

- diaphragm function

- lung-perfusion

- small airways function

- systemic inflammation

3) To investigate which patient characteristics at baseline predicts response

to the LVRC treatment at 3 months follow up.

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. However, patient-based outcomes besides quality of life questionnaires are hardly measured after intervention treatments for COPD. Furthermore, the exact underlying physiological mechanism of the LVR-coil treatment is unknown. 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%.

Study objective

The objectives of the study are to gain more knowledge on 1) the effect of the LVRC treatment on patient-based outcomes like physical activity, 2) the underlying physiological mechanism of the treatment, and 3) the predictors of response to the treatment at baseline.

Study design

This study is a non-randomised open label multi-center intervention study.

Intervention

Bilateral bronchoscopic lung volume reduction treatment with RePneu coils.

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. Part of this new study is to try to identify which group of patients respond to the treatment and which patients do not. Therefore, it is possible that a patient will not receive any benefits from the treatment.

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

1) Diagnosis of COPD
2) FEV1%pred <45% and FEV1/FVC <60%
3) RV/TLC >55%
4) TLC%pred >100% AND RV%pred >175%
5) Dyspnea scoring >=2 on mMRC scale of 0-4.
6) Stopped smoking for at least 6 months prior to entering the study.
7) 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.
8) Received Influenza vaccinations consistent with local recommendations and/or policy.
9) Read, understood and signed the Informed Consent form.

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 and/or PaO2 < 6.0 kPa (on room air).
3) Subject has a history of recurrent clinically significant respiratory infections, defined as 3 or more hospitalizations for respiratory infection during the year prior to enrolment.
4) Subject has severe pulmonary hypertension defined by right ventricular systolic pressure >45 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 conscious sedation or general anaesthesia.
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 >10 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 prior to procedure.
16) Subject has a known 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.
19) Alfa-1 AT deficiency
20) Medical history of asthma

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):	09-03-2015
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	13-01-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-02-2017
Application type:	Amendment
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	NL49716.042.14