LVRC IDE Crossover Study

Published: 04-12-2013
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The primary objective of this study is to provide the LVRC procedure and safety and effectiveness follow up to qualifying subjects who were enrolled as Control Subjects in and completed the 12 month visit of the Lung Volume Reduction Coil Treatment...

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

Summary

ID

NL-OMON38708

Source
ToetsingOnline

Brief title
CROSS-OVER RENEW 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: PneumRx;CA;USA

Intervention

Keyword: bronchoscopy, COPD, emphysema, lung volume reduction

Outcome measures

Primary outcome

The primary objective of this study is to provide the LVRC procedure and safety

and effectiveness follow up to qualifying subjects who were enrolled as Control

Subjects in and completed the 12 month visit of the Lung Volume Reduction Coil

Treatment in Patients with Emphysema (RENEW) Study.

Secondary outcome

Descriptive statistics will be used to evaluate the data, including differences

from Baseline to 12 months in 6MWT and SGRQ, and safety.

Study description

Background summary

Current treatment of emphysema (COPD gold III-IV) generally is limited to palliative measures that include supplemental oxygen, bronchodilators, anti-inflammatory drugs and pulmonary rehabilitation or to lung transplantation. 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.

Study objective

The primary objective of this study is to provide the LVRC procedure and safety and effectiveness follow up to qualifying subjects who were enrolled as Control Subjects in and completed the 12 month visit of the Lung Volume Reduction Coil Treatment in Patients with Emphysema (RENEW) Study.

Study design

This will be a prospective, multicenter, open label, single-arm study.

Intervention

Nitinol Lung Volume Ruduction Coils will be placed in both lungs during two bronchoscopic procedures, aiming to induce a volume reduction and therefore aiming to improve the clinical status of emphysema patients with severe hyperinflation by improving pulmonary mechanics.

Study burden and risks

The patients that will be screened for potential participation will recieve pulmonary function testing, thoracic HRCT scanning and an outpatient visit. The patients that will be included will have to come to our outpatient clinic, perform pulmonary function testing, a 6 min walking test, thoracic x-ray and testing of blood samples and arterial bloodgas. For the actual treatment with bronchoscopy under general anesthesia the patients will stay two times two nights in our hospital. For the follow-up, 1 CT scan at 12 months and outpatient clinic visits will be needed with additional pulmonary function and exercise testing. 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 lung volume reduction coil treatment does it seem possible to give relieve of shortness of breath and improvement in excercise performance. Furthermore can this technique be used as a 'bridge' to lung transplantation 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 actual treatment with the LVR-Coils can cause: airway bleeding, airway infections and fever, pneumothorax, cough (that might result in an additional bronchoscopy to remove the coils), or death as a result of one of these complications.

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

Subject paticipated in the RENEW study and was randomized for the CONTROLgroup. This patient completed 12 month follow-up visit.
>=35 years of age. CT scan indicates bilateral emphysema. Subject has post-bronchodilator FEV1 <=45% predicted. Subject has Total Lung Capacity >100% predicted. Subject has residual volume (RV) >=225% predicted. Subject has marked dyspnea scoring >=2 on mMRC scale of 0-4.

Exclusion criteria

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. Subject has a change in FEV1 >20% (or, for subjects with pre-bronchodilator FEV1 below 1 L, a change of > 200 mL) post-bronchodilator. Subject has DLCO <20% of predicted. Subject has severe gas exchange abnormalities as defined by: PaCO2 >55 mm Hg, PaO2 <45mm Hg on room air. Subject has a history of recurrent clinically significant respiratory infections, defined as 3 hospitalizations for respiratory infection during the year prior to enrollment. Subject has severe pulmonary hypertension defined by right ventricular systolic pressure >50 mm Hg via right heart catheterization and/or echocardiogram. Subject has an inability to walk >140 meters. 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. Subject has clinically significant bronchiectasis. Subject has giant bullae >1/3 lung volume. Subject has had previous LVR surgery, lungtransplantation, lobectomy , LVR devices or other devices to treat COPD in either lung. Subject has been involved in pulmonary drug or device studies within 30

days prior to this study. Subject is taking >20 mg prednisone (or equivalent dose of a similar steroid) daily. Subject requires high level chronic immunomodulatory therapy to treat a moderate to severe chronic inflammatory autoimmune disorder. Subject is on an antiplatelet agent (such as Plavix) or anticoagulant therapy (such as heparin or Coumadin) which cannot be stopped for seven (7) days prior to procedure. Subject has a sensitivity or allergy to Nickel Subject has been diagnosed with alpha-1 antitrypsin deficiency (AATD).

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	03-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-08-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-11-2015
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	NL46553.042.13
Other	volgt