Evaluation of the PneumRx, Inc. Lung Volume Reduction Device for the Treatment of Subjects with Homogeneous Emphysema

Published: 24-10-2011
Last updated: 29-04-2024

To evaluate the mechanism of action and effecacy of the Lung Volume Reduction Coil to improve QOL pulmonary function for homogeneous emphysema subjects with severe hyperinflation.

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

Summary

ID

NL-OMON35800

Source
ToetsingOnline

Brief title
LVR-coil study CLN0012

Condition

- Respiratory disorders NEC

Synonym
COPD, Emphysema

Research involving
Human

Sponsors and support

Primary sponsor: PneumRx

Source(s) of monetary or material Support: Biotechnologische industrie

Intervention

Keyword: bronchoscopy, COPD, homogeneous emphysema, lung volume reduction

Outcome measures

Primary outcome

Differences between baseline visit and follow-up visit Six minutes walk test

(m) .

Secondary outcome

Differences between baseline visit and 6 month follow-up visit PFT

measurements and quality of Life parameters (questionnaires).

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 homogeneous emphysema would provide meaningful clinical benefit.

Study objective

To evaluate the mechanism of action and effecacy of the Lung Volume Reduction Coil to improve QOL pulmonary function for homogeneous emphysema subjects with severe hyperinflation.

Study design

single-center single arm study

Intervention

Nitinol Lung Volume Ruduction Coils will be placed in both lungs during two bronchoscopic procedures, with an interval of 2 months, 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 (both are often already available) 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 days in our hospital. For the follow-up, 1 CT scan, 3 pulmonary function tests, three 6 min walking tests and 3 outpatient clinic visits will be needed 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 airway bypass procedure 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 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

Public
PneumRx

530 Logue Avenue
Mountain View 94043 California
US
Scientific
PneumRx

530 Logue Avenue

Mountain View 94043 California
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Homogeneous emphysema on CT-thorax
Post-bronchodilator FEV1 < 35% predicted
Total Lung Capacity > 120% predicted
Residual Volume > 225% predicted
mMRC dyspnea score >2
Stopped smoking > 6 months

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 > 20 mg prednisone (or similar steroid) daily
Patient has evidence of other disease that may compromise survival (such as lung cancer, renal failure etc)

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):	30-11-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	24-10-2011
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	NL36612.042.11