# Feasibility Study of the PneumRx, Inc. Lung Volume Reduction Coil for the Treatment of Emphysema

Published: 03-12-2009
Last updated: 04-05-2024

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

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

## Summary

### ID

NL-OMON36664

**Source**
ToetsingOnline

**Brief title**
LVR-Coil Safety and Efficacy Study

### Condition

- Respiratory disorders NEC

**Synonym**
COPD, Emphysema

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** PneumRx, Inc
**Source(s) of monetary or material Support:** Biotechnologische industrie

## Intervention

**Keyword:** Bronchoscopy, COPD, Emphysema, Lung volume reduction

## Outcome measures

### Primary outcome

Safety

Improvement in St. George's Respiratory Questionnaire (SGRQ) total score

### Secondary outcome

Differences between baseline visit and 6 month follow-up visit

FEV1 and FVC (L)

RV/TLC (%)

Residual Volume (L)

Six minutes walk test (m)

modified Medical Research Counsil Dyspnea Scale (mMRC)

Oxygen use

# 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 a heterogeneous pattern of emphysema might be benefited 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 safety and effecacy of the Lung Volume Reduction Coil to improve QOL pulmonary function for emphysema subjects with severe hyperinflation.

## Study design

Internationale multi-center single arm feasibility intervention trial

## Intervention

Nitinol Lung Volume Ruduction Coils will be placed in both lungs during two bronchoscopic procedures, with an interval of 1 month, 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, 4 pulmonary function tests, four 6 min walking tests and 4 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

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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Heterogeneous emphysema on CT-thorax
Post-bronchodilator FEV1 < 45% predicted
Total Lung Capacity > 100% predicted
mMRC dyspnea score >2
Stopped smoking > 8 weeks

## Exclusion criteria

History of recurrent respiratory infections and/or bronchiectasis
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

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|---|---|
| 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): | 23-11-2009 |
| Enrollment: | 20 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Generic name: | Nitinol Lung Volume Reduction-Coil |
| Registration: | No |

# Ethics review

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| Approved WMO Date: | 03-12-2009 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 02-05-2011 |
| 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 | NL30327.042.09 |