Evaluation of the Free Flow Medical Lung Tensioning Device System for the Treatment of Severe Emphysema

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The aim of this study is to 1) evaluate the safety and feasibility of lung volume reduction using LTDs and 1) evaluate the effectiveness

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

Summary

ID

NL-OMON55012

Source
ToetsingOnline

Brief title
EFFORT trial

Condition

- Respiratory disorders NEC

Synonym
Emphysema; COPD (Chronic Obstructive Pulmonary Disease)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bronchoscopy, COPD, Emphysema, Lungvolume reduction

Outcome measures

Primary outcome

1) To evaluate the safety of the LTD in COPD patients with heterogeneous and homogeneous emphysema by evaluating the type and frequency of device-related and procedure-related AE experienced during and following LTD placement through the 3-month visit.

2) To evaluate the feasibility of the LTD in COPD patients with heterogeneous and homogeneous emphysema by measuring the frequencies of successful and unsuccessful intended LTD placements.

Secondary outcome

1) To investigate the change between baseline and 3 month follow up after LTD treatment in:

- Patient reported symptoms using dedicated questionnaires (SGRQ, mMRC, CAT)

- Pulmonary function outcomes:

- 6 minute walking distance (6MWD)

- Change in treatment target lobar volume on HRCT

- Percentage of patients reaching the minimal important difference for: FEV1, RV, 6MWD, SGRQ

Study description

Background summary

Patients suffering from severe empysema have limited treatment options. The standard of care is aimed at symptom reduction using (inhaltion)medication and improving exercisice tolerance and disease acceptance. There are two invasive surgical treatments available: lung volume reduction surgery and lung transplantation. However, only a small group of patients is eligable for either one of these treatment options. A, less invasive, alternative is endoscopic lung volume reduction (ELVR). To date, ELVR using one-way valves is the only ELVR treatment option adopted into treatment guideliness. However, this treatment is only effective in patients without contralateral ventilation between the treatment lobe and the ipsilateral lobe. Endobronchial coils have been studied as an ELVR treatment option, in which intact fissures is not a requirement. The results are promising, but the response rate 1 year after treatment is around 40-50%. The Lung Tensioning Device (LTD) is a endobronchial implantable device and can be regarded as a second degeration design of the endobronchial coil. The design is improved to optimize the compression of the treated lung parts.

Study objective

The aim of this study is to 1) evaluate the safety and feasibility of lung volume reduction using LTDs and 1) evaluate the effectiveness

Study design

This study is a single-arm, prospective, open-label, multi-center trial

Intervention

Bilateral endoscopic lung volume reduction with Free Flow Medical LTDs

Study burden and risks

Patients enrolled in the study will perform baseline testing, including pulmonary function testing (PFT), chest HRCT, blood draw, arterial blood gas, 6 minute walking test (6MWD) and quality of life questionnaires. If a patient fulfils the study criteria, the patient will undergo a bronchoscopic intervention with placement of LTD(s) in one lung. Six weeks after the bronchoscopic intervention patients visit the hospital for follow up testing. Next, patients will undergo the second bronchoscopic intervention with placement of LTD(s) in the other treatment lobe. After 3 months patients will complete the endpoint follow-up assessment (PFT, HRCT, 6MWD, arterial blood gas and questionnaires). Thereafter, patients will be followed for 6 and 12 months after treatment. No previous studies with the LTD have been done therefore the exact risks are unknown. The main risks are expected to equal to existing treatments using a nitinol wire device (LVR-coil), and can be related to the bronchoscopic placement of the LTDs and may include pneumothorax, hemoptysis,

respiratory tract infections and COPD exacerbations. Inclusion in the study may lead to improved lung function, exercise tolerability and/or symptom relieve. However, no perceived or measured benefit from this treatment is also possible.

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. >= 40 years of age
3. FEV1/FVC <= 70%
4. Post-bronchodilator FEV1 <= 45% of predicted
5. Total Lung Capacity > 100% of predicted
6. Residual Volume (RV) > 175% of predicted
7. RV/TLC > 55%

8. Marked dyspnea defined by a score of >= 2 on mMRC dyspnea scale of 0-4
9. Emphysema with >= 20% destruction (-950HU) of one or more lobe(s)
10. Stopped smoking for >= 6 months prior to entering the study
11. Completed a pulmonary rehabilitation program prior to entering the study and/or have regular (at least once a week) physiotherapy
12. Ability to read, understand and sign the informed consent form

Exclusion criteria

1. History of recurrent clinically significant respiratory infections and/or COPD exacerbations, defined as >= 2 hospitalizations for respiratory infections and/or COPD exacerbations during the year prior to enrolment
2. History of recurrent clinically significant respiratory infections and/or COPD exacerbations, defined as >= 3 courses of prednisolone and/or antibiotics for respiratory infections and/or COPD exacerbations during the year prior to enrolment
3. Clinically significant bronchiectasis
4. Severe gas exchange abnormalities defined by PaCO2 > 7.0 kPa (52 mmHg) and/or PaO2 < 7.0 kPa (52 mmHg) (measured on room air)
5. >= 10 mg prednisone (or equivalent dose of other corticosteroids) daily
6. Inability to walk > 140 meters in 6 minutes
7. Known pulmonary hypertension defined by right ventricular systolic pressure > 45 mmHg and/or evidence of pulmonary hypertension or right ventricular failure on echocardiogram
8. Significant paraseptal emphysema
9. Giant bullae (>1/3 of lung volume)
10. Medical history of asthma
11. Underwent previous LVRS, lobectomy, pneumonectomy or lung transplant
12. Underwent previous treatment with thermal vapor ablation, AeriSeal, Cryospray, endobronchial coils or endobronchial valves (if still implanted)
13. Evidence of other disease(s) that have a predicted survival of less than one year
14. Inability to tolerate bronchoscopy under general anaesthesia
15. Maintenance antiplatelet (except aspirin/Ascal) or anticoagulant therapy (such as warfarin, Coumadin, heparin, LMWH, DOACs, etc) which cannot be permanently stopped prior to entering the study
16. Pregnant, lactating or plans to become pregnant within the study timeframe
17. Known sensitivity to drugs required to perform bronchoscopy under general anaesthesia
18. Any other disease(s), condition(s) or habit(s) that would interfere with completion of study and follow up assessments, would increase the risks of bronchoscopy or assessments or in the judgment of the investigator would potentially interfere with the treatment
19. Known Nickel, Titanium, or Nitinol allergy

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):	21-06-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Lung Tensioning Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-11-2021
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
ClinicalTrials.gov	NCT04520152
CCMO	NL73201.042.21