A prospective randomized controlled trial on the Systemic effects of bronchoscopic Lung Volume reduction in patients with severe Emphysema.

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To study in detail the impact and optimal timing of pulmonary rehabilitation (PR) on exercise physiology and patient-reported outcomes and the impact of the bronchoscopic lung volume reduction treatment using endobronchial valves (EBV) on...

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

Summary

ID

NL-OMON52962

Source
ToetsingOnline

Brief title
SOLVE 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: Longfonds

Intervention

Keyword: Bronchoscopy, COPD, Lung volume reduction, Pulmonary Rehabilition

Outcome measures

Primary outcome

The main study parameter is the difference in change in endurance time measured by an endurance cycle test between the EBV treatment group and the bronchoscopic lung volume reduction + rehabilitation group (EBV+PR).

Secondary outcome

Pulmonary rehabilitation

• the difference between the EBV treatment group and the EBV+PR group in change in:

-Physical activity measured by accelerometry

-Lung function measured by spirometry, bodyplehtysmography and diffusion capacity

-Exercise capacity measured by an incremental cycle ergometer test and 6-minute walk distance test

-Peripheral muscle strength measured by a leg press test

-Depression severity and anxiety level measured by the HADS and fatigue level measured by the CIS questionnaire.

• the differences in above mentioned variables between the patients who undergo PR before EBV treatment versus the patients who undergo PR after EBV treatment.

Patient-reported outcomes

• the change after EBV treatment in depression severity measured by the HADS questionnaire

• the change after EBV treatment in anxiety level measured by the HADS questionnaire

• the change after EBV treatment in fatigue level measured by the CIS questionnaire.

Cardiopulmonary function:

• the change after EBV treatment in RVEDVI as measured with cardiac MRI.

• the change after EBV treatment in cardiac structural, volumetric, and functional changes of the right ventricle, left ventricle, and left atrium; local and regional measures of aortic stiffness; pulmonary pulsatility as measured with cardiac MRI

• the relative contribution of improvement in RVEDVI to the improvement in exercise capacity or physical activity after EBV treatment.

• the change in RVEDVI as function of actual lobar volume reduction (measured on CT and Bodyplethysmography).

Metabolism and change in body composition

• the change after EBV treatment in fat-free mass index, fat mass, and fat distribution measured by a dexa scan.

• the relationship between the change in muscle volume measured on CT scan and the change in exercise capacity,

• the relationship between the change in muscle volume measured on CT scan and

the change in exercise capacity, change in lung mechanics (measured by HRCT and bodyplethysmography) and cardiac alteration.

• In muscle and fat biopsies before and after EBV we will perform a detailed histological and biochemical analysis of muscle fiber type composition, mitochondrial density, master regulators of muscle oxidative programming, mitochondrial respiration and lipid droplets.

Study description

Background summary

The published clinical trials investigating the bronchoscopic lung volume reduction, showing important patient-related improvements in efficacy, led to the acknowledgement of the treatment in the GOLD-COPD2017 guidelines. Interaction with pulmonary rehabilitation, impact on patient-reported outcomes, physical activity, and extrapulmonary consequences are all topics to gain more insight in. This importantly, to further develop and optimize this innovative and personalized therapy.

Study objective

To study in detail the impact and optimal timing of pulmonary rehabilitation (PR) on exercise physiology and patient-reported outcomes and the impact of the bronchoscopic lung volume reduction treatment using endobronchial valves (EBV) on cardiopulmonary function, metabolism and changes in body composition.

Study design

This study is a randomized controlled trial with 3 study-arms. Group 1 will first follow a PR program and afterwards undergo the EBV treatment. Group 2 will first undergo the EBV treatment and approximately 8 weeks later will follow a PR program. Group 3 will only undergo the EBV treatment (and can choose to follow a PR program after completing the 6 month FU visit).

Intervention

Most patients will undergo a bronchoscopic lung volume reduction treatment using endobronchial valves and a pulmonary rehabilitation program. One group of patient will under a bronchoscopic lung volume reduction treatment using

endobronchial valves and can choose whether they also want to follow a pulmonary rehabilitation program afterwards.

Study burden and risks

This study has no major risks for the participating patients. The patients will be exposed to additional exercise capacity and physical activity measurements, 3 additional questionnaires, a CT scan of the quadriceps muscle, a DEXA scan and peripheral blood collection. Furthermore, a subgroup of patients will be exposed to a cardiac MRI or muscle and fat biopsies. Patient can directly benefit from the EBV treatment and the pulmonary rehabilitation program. Indirect benefit might be achieved, because, at a group level we will learn more about this novel treatment for our severe emphysema patients and will be able to further optimize this 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

- COPD.
- FEV1 <=45%pred AND FEV1/FVC <70%.
- TLC >100%pred AND RV>175%pred.
- CAT >=10.
- >50% emphysema destruction @-910HU.
- >95% complete major fissure measured by quantitative CT analysis.
- Non-smoking >6 months.
- Signed informed consent.

Exclusion criteria

- PaCO2>8.0 kPa, or PaO2<6.0kPa.
- 6-minute walk test <160m.
- Significant chronic bronchitis, bronchiectasis, or other infectious lung disease.
- 3 or more hospitalizations due to pulmonary infection within last 12 months before baseline assessments
- Previous lobectomy, LVRS, or lung transplantation.
- LVEF<45% and or RVSP>50mmHg.
- Anticoagulant therapy which cannot be weaned off prior to procedure.
- Patient is significantly immunodeficient.
- Involved in other pulmonary drug studies within 30 days prior to this study.
- Pulmonary nodule which requires intervention
- Any disease or condition that interferes with completion of initial or follow-up assessments

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2019
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-07-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-04-2022
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	NCT03474471
CCMO	NL65304.042.18