Bronchoscopic Lung Volume reduction with endobronchial valves using best responder criteria in patients with severe COPD

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To investigate both the clinical and economical(-healthcare evaluation) improvement of BVR using best responder criteria in patients with severe COPD.

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

Summary

ID

NL-OMON39131

Source
ToetsingOnline

Brief title
STELVIO Trial

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: ZonMW/VEMI 80-82305-97-11018

Intervention

Keyword: Bronchoscopy, COPD, Lungvolume Reduction, Valves

Outcome measures

Primary outcome

Clinical Evaluation: a clinical significant improvement of FVC, FEV1 and 6

minutes walk test.

Economic Evaluation: total costs of the bronchoscopic lung volume reduction

compared to usual care and (historical) costs of LVRS.

Secondary outcome

Quality of life (measured by SGRQ, CCQ)

Target lobar volume change on a full inspiratory thin slice CT scan

Study description

Background summary

Patients with end-stage COPD suffer form severe dyspnea and a poor quality of life, with no current effective medical treatment. Only for a very small, highly selective group of COPD patients, very invasive surgical procedures like lung volume reduction surgery (LVRS) or lungtransplantation are available. Recently, a non-surgical bronchoscopic treatment modality called bronchoscopic lungvolume reduction (BVR) using one-way endobronchial valves to achieve lung volume reduction has come available. BVR is highly effective in a subset of patients with COPD, with heterogeneous distributed emphysema with intact intralobular fissures present on CT. In this grant application we will investigate the efficacy of BVR in patients with severe heterogeneous emphysema compared to usual care.

Study objective

To investigate both the clinical and economical(-healthcare evaluation)

improvement of BVR using best responder criteria in patients with severe COPD.

Study design

Prospective, randomized (1:1) clinical intervention trial with a crossover of the controlgroup to treatment.

Intervention

Placement of oneway-valves during a bronchoscopy. (Bronchoscopic lungvolume reduction)

Study burden and risks

SCREENING: clinic visit; ± 5 hours (including "rest" periods between examinations): lung function, dynamic hyperinflation testing, 6 min walk test, record of physical activity, consult anesthesiologist, completing questionnaires and CT scan of the lungs.

Enrolled patients: Hospital stay :3 days (2 nights) , control X-ray and a bronchoscopic lung volume reduction under anesthesia.
BVR using EBVs ultimately results in >75% volume loss of the treated lobe, thereby causing transient symptoms that resolve within 4 weeks after the BVR. By inducing this significant volume reduction the major risks involved are: Pneumothorax (1 in 10 patients) for which chest drainage is required, transient (1-3 days) chestpain (1 in 2 patients), transient (1-7 days) dyspnea (1 in 4 patients). This significant volume loss of the treated lobe results in an increase in FEV1 and FVC, with decreasing RV, resulting in a significant reduction in dyspnea and improvement in quality of life (as measured with the SGRQ) and a better exercise tolerance (as measured with the 6MWT).

FOLLOW-UP: 2 times a visit of ± 3-5 hours, lung function, dynamic hyperinflation testing, 6 min walk test, chest X, completing questionnaires and recording of physical activity and CT scan of the lungs

The included COPD patients all have a very serious limitation of their daily actvities. All included patients have a severe limitation of their activities of daily living. With the BVR procedure does it seem possible to give -at least temporarily- relieve of shortness of breath and improvement in expercise performance.

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

Heterogeneous emphysema on CT scan
Complete fissures on CT scan
Signed Informed Consen

Exclusion criteria

Hypercapnia defined by PaCO2>8.0 kPa, or hypoxemia defined by PaO2<6.0kPa, both measured on room air.
6MWT <140 meters
Previous LVR-surgery, lung transplantation or lobectomy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2011
Enrollment:	68
Type:	Actual

Medical products/devices used

Generic name:	Endobronchial one-way valve (Zephyr)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-03-2013
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	NL35716.042.11
Other	NTR/TC2876