Bronchoscopische Longvolume Reductie door middel van éénrichtingsventielen in patiënten met ernstig COPD.

Gepubliceerd: 28-04-2011 Laatst bijgewerkt: 18-08-2022

Primary Objective: In this trial we will investigate the efficacy of BVR using best responder criteria in patients with severe heterogeneous emphysema compared to usual care.
Secondary Objective: Economic evaluation: Estimation of costs of BVR...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23581

Bron
NTR

Verkorte titel
STELVIO trial

Aandoening

COPD
Emphysema
Emfyseem

Ondersteuning

Primaire sponsor: UMC-Groningen, Pulmonary diseases
Overige ondersteuning: ZonMW/VEMI 80-82305-97-11018
UMC-Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Statistical and clinical significant improvement in both the FVC and FEV1 as well as in the 6 minute walk test.

Toelichting onderzoek

Achtergrond van het onderzoek

Title:

Bronchoscopic Lung Volume reduction with endobronchial valves using best responder criteria in patients with severe COPD: “STEVIO-trial”.

Primary Objective:

We will investigate the efficacy of BVR using best responder criteria in patients with severe heterogeneous emphysema compared to usual care.

Secondary Objective:

Economic evaluation: Estimation of costs of BVR compared to care as usual and (historical) costs of LVRS.

Study Design:

Prospective, randomized (1:1) clinical intervention single center trial with a crossover of the control group to treatment.

Study Population:

22 Patients with COPD Gold stage III-IV, who stopped smoking at least 6 months ago and who have severe dyspnea despite optimal medical treatment with heterogeneous distributed emphysema with intact interlobular fissures present on thin slice CT scan.

Device:

Zephyr (PulmonX, USA) endobronchial valve. Follow-Up 6 months, with crossover for the control group after 6 months to active treatment.

Duration:

24 months.

Primary endpoint:

Statistical and clinical significant improvement in both the FVC and FEV1 as well as in the 6 minute walk test.

Doel van het onderzoek

Primary Objective:

In this trial we will investigate the efficacy of BVR using best responder criteria in patients with severe heterogeneous emphysema compared to usual care.

Secondary Objective:

Economic evaluation: Estimation of costs of BVR compared to care as usual and (historical) costs of LVRS.

Onderzoeksopzet

Follow-up after treatment is 6 months, crossover for control is also after 6 months

Onderzoeksproduct en/of interventie

Bronchoscopic lung volume reduction using Zephyr one-way endobronchial valves (PulmonX USA).

There will be a crossover of the control group to treatment.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient > 35 years of age;

2. CT scan indicates heterogeneous emphysema (>25% difference in destruction score between ipsilateral lobes);

3. CT shows ≥ 60% destruction of the target lobe;

4. CT scan indicates intact fissures as assessed on the sagittal reconstructions of a thin slice CT, or previously performed assessment of collateral flow show absence of collateral ventilation;

5. Post- bronchodilator FEV1 <60% predicted;

6. Post- bronchodilator TLC>100% en RV>150%;

7. Dyspnea score of ≥2 on the mMRC scale of 0-4;

8. Patient has stopped smoking for a minimum of 6 months prior to entering the study;

9. Signed informed Consent;

10. Subject is willing and able to comply with all study testing and procedures according to protocol and guidelines;

11. Lobar exclusion during EBV treatment is achieved.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Hypercapnia defined by PaCO2>8.0 kPa, or hypoxemia defined by PaO2<6.0kPa, both measured on room air;

2. 6MWT <140 meters;

3. Previous LVR-surgery, lung transplantation or lobectomy;

4. Patient is on an antiplatelet agent (such as Plavix) or anticoagulant therapy (such as LMWH or coumarins) or has not been weaned off prior to procedure;

5. Involved in other pulmonary drug studies within 30 days prior to this study;

6. Evidence of other disease that may compromise survival, would interfere with completion of study, follow up assessments or that would adversely affect outcomes, such as lung cancer, and/or ASA class >III.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	68
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2738
NTR-old	NTR2876
Ander register	ZonMW/VEMI : 80-82305-97-11018
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A