Proactive treatment of collateral ventilation in CV-positive emphysema patients before EBV treatment

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

Samenvatting

ID

NL-OMON23885

Bron
NTR

Verkorte titel
MIND THE GAP

Aandoening

Chronic Obstructive Pulmonary Disease
Emphysema

Ondersteuning

Primaire sponsor: Investigator initiated study, Univeristy Medical Center Groningen
Overige ondersteuning: Pulmonx Inc, unrestricted grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility: Evidence of targeted lung volume reduction (TLVR) on CT scan at 1 month Follow Up.

Toelichting onderzoek

Achtergrond van het onderzoek

Title:

Study of proactive treatment of collateral ventilation in CV-positive emphysema patients before EBV treatment (MIND THE GAP)

Primary Objective:

1.To investigate the feasibility of injecting autologeous blood or blood derived products into the interlobar collateral ventilation channels region to make the target lobe suitable for endobronchial valve treatment.

Secondary Objectives:

2.To investigate the safety of injecting autologeous blood or blood derived products into the interlobar collateral ventilation channels region to make the target lobe suitable for endobronchial valve treatment.

3.To investigate the effectiveness of injecting autologeous blood or blood derived products into the interlobar collateral ventilation channels region to make the target lobe suitable for endobronchial valve treatment.

Study Design:

Prospective, single arm open label intervention study.

Study Population:

20 patients with heterogeneous emphysema and with 70-90% complete fissures detected on a CT scan.

Intervention:

The injection of autologeous blood or blood derived products into the interlobar collateral ventilation channels region to convert CV(+) lobes into CV(-) lobes.

Duration:

3 months follow-up, Study duration:24 months.

Primary endpoint:

Feasibility: Evidence of targeted lung volume reduction (TLVR) on CT scan at 1 month Follow Up.

Doel van het onderzoek

The overall objective of the study is investigate if it is possible to convert CV(+) patients to CV(-) patients with use of autologeous blood or alternatively blood derived products that closes the collateral channels. And thus to develop a bronchoscopic procedure for patients with heterogeneous emphysema who have collateral flow by combining the established EBV treatment with the injection of autologeous blood or blood derived products to close of the collateral channels.

Onderzoeksopzet

3 months follow-up after the procedure.

Onderzoeksproduct en/of interventie

The injection of autologeous blood or blood derived products into the interlobar collateral ventilation channels region to convert CV(+) lobes into CV(-) lobes.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1.Diagnosis of upper or lower lobe heterogeneous emphysema with a difference in heterogeneity of ¡Ý 25% in destruction at -950HU between ipsilateral lobes.

2.Subjects of both genders of at least 35 years of age at the time of the baseline visit.

3.Understand and voluntarily sign a patient informed consent form.

4.15 % predicted ¡Ü FEV1¡Ü 45% predicted.

5.RV >= 175% predicted, and TLC >= 100% predicted and RV/TLC >= 55% predicted.

6.6MWT >= 140 meters.

7.Dyspnea score of >= 2 on the mMRC scale of 0-4.

8.Non-smoker > 8 weeks prior to signing the informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1.Evidence of active pulmonary infection.

2.Evidence of clinically significant bronchiectasis.

3.History of more than 3 exacerbations with hospitalizations over the past 12 months.

4.Evidence of pulmonary hypertension (sPAP > 45mmHg).

5.Subject has DLCO <20% of predicted.

6.Myocardial infarction or other relevant cardiovascular events in the past 6 months.

7.Prior lung surgery, Lung volume reduction surgery, lung transplantation, lobectomy, or pneumonectomy.

8.Prior endoscopic lung volume reduction.

9.Unstable pulmonary nodule requiring follow-up.

10.Pregnant or nursing women.

11.Hypercapnia defined by PaCO2 > 8.0kPa, or Hypoxemia defined by PaO2 < 6.0kPa, both measured on room air.

12.>20mg prednisolon (or equivalent) use/days.

13.Any disease with high probability of mortality within 24 months.

14.Patient is on an antiplatelet agent (such as Plavix) or anticoagulant therapy (such as LMWH or coumarins).

15.Patient was involved in other pulmonary drug studies within 30 days prior to this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-11-2014
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41669
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4905
NTR-old	NTR5007
CCMO	NL47731.042.14
OMON	NL-OMON41669

Resultaten