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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23885

Source
NTR

Brief title
MIND THE GAP

Health condition

Chronic Obstructive Pulmonary Disease
Emphysema

Sponsors and support

Primary sponsor: Investigator initiated study, Univeristy Medical Center Groningen
Source(s) of monetary or material Support: Pulmonx Inc, unrestricted grant

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Safety: The number and type of procedure-related (serious) adverse events within 3 months after the procedure.

Effectiveness: Change in TLVR, lung function, exercise capacity and quality of life at 3 months Follow Up.

Study description

Background summary

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.

Study objective

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.

Study design

3 months follow-up after the procedure.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-12-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41669
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results