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

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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...

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

Summary

ID

NL-OMON41669

Source
ToetsingOnline

Brief title
MIND THE GAP

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: Ministerie van OC&W,Mede mogelijk door een unrestricted Grant van PulmonX Inc;CA;USA.

Intervention

Keyword: Blood, Bronchoscopy, COPD, Lungvolume reduction

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

Of all current bronchoscopic lung volume reduction (BLVR) strategies the endobronchial valve (EBV) approach can result in the most pronounced treatment effects in patients with upper or lower lobe heterogeneous emphysema. This is mainly due to the total lobar occlusion, resulting in a long volume reduction of an entire lobe. However, EBV treatment is only this highly efficacious in patients with absence of collateral ventilation (CV) between the treatment lobe and the adjacent lobe(s). Only a minority of patients with emphysema have no CV, with figures in patients with heterogeneous emphysema ranging from 10-30%. Because the presence of CV is the 'bane' of the effect of EBV therapy, there are a number of so called non-blocking techniques under development, which have proven that sealing compounds can be delivered to the lung. Also BLVR efforts with autologeous blood from countries where there is no access to devices or just creative thinking is conducted, or the use of tissue-col or fibrin-glue to try to treat fistulas, both show feasibility and safety of substance delivery to the airways and lungs. A big step forward and great opportunity to improve

overall efficacy of BLVR is to combine treatment modalities aiming to close the dependent collateral channels by using fluid substances to close off collateral channels and then proceed with EBV therapy to induce lobar collapse, and thus maximal treatment effect.

Study objective

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.

Intervention

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

Study burden and risks

This study is the first to investigate the feasibility of closing the collateral ventilation channels by autologeous blood or blood derived products to convert positive collateral ventilation to negative collateral ventilation. Therefore, it is possible that the patients will not receive any benefits from participation in this trial if the procedure will not lead to a conversion to CV(-).
Risks associated with the Chartis measurement and the placement of EBVs mainly include the risk associated with routine bronchoscopy, like sore throat and bronchitis. The placement of the EBV is associated with an increased risk of a pneumothorax. The specific risks to the use of blood or blood derived products include infective COPD exacerbation and pneumonia.
The patients who will participate in this trial have limited treatment options. Due to their type of emphysema and incomplete pulmonary fissures other bronchoscopic lung volume reduction treatments are not possible. Patients will

only be offered entry into the MIND THE GAP trial if the consensus decision of the bronchoscopic intervention is that participating in this trial is the best option for the patient. Other trials have shown that bronchoscopy is a very safe procedure in severe emphysema patients. The advantage of the use of patient*s own blood is that it does not require foreign implants, and represents dramatic cost savings. The injection of autologeous blood or blood derived products could potentially successful convert CV(+) to CV(-) and consequently the patient can be succesfully treated with the EBV. Potentially, BLVR could result in the majority of patients in a clinical significant increase in FEV1 and FVC, with decreasing RV, resulting in a significant reduction in dyspnea and improvement in quality of life, and a better exercise tolerance.

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

1. Diagnosis of upper or lower lobe heterogeneous emphysema with a difference in heterogeneity of >= 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 <= FEV1<= 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

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	01-10-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-01-2016
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

ID: 23885
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL47731.042.14

Register	ID
Other	wordt tzt nog geregistreerd in het clinical trial register
OMON	NL-OMON23885