A feasibility and safety study of bronchoscopic intrabullous autologous blood instillation for the treatment of severe bullous emphysema.

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To assess the safety and effects of bronchoscopic intrabullous blood instillation in patients with bullous emphysema on lung function, quality of life measures, functional measures and CT measured lung volumes.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38731

Source
ToetsingOnline

Brief title
BIABI study

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

Intervention

Keyword: Blood, Bronchoscopy, COPD, Lungvolume reduction

Outcome measures

Primary outcome

Change in RV 6 months following treatment

Secondary outcome

Change in TLC 6 months following treatment

Change in RV/TLC ratio 6 months following treatment

Changes in FEV1 and FVC 6 months following treatment

Change in the intrathoracic gas volume 6 months following treatment

Change in DLCOc 6 months following treatment

Change in the SGRQ score 6 months following treatment

Change in the mMRC score 6 months following treatment

Change in the 6MWD 6 months following treatment

Changes in the above mentioned lung function, functional and quality of life

outcome measures at 3 months.

Change in CT measured lung volumes 6 months following treatment

Study description

Background summary

Patients with end-stage COPD suffer from 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 lung transplantation are available.

Furthermore for patients with severe bullous emphysema, removal of giant bullae (bullectomy) has been a standard treatment in selected patients for many years. Unfortunately, bullectomy is major surgery and requires general anesthesia, a prolonged hospital stay, and is associated with a significant risk of complications.
Less invasive and safer approaches to try and shrink the size of bulla(e) without surgery are needed, and some early work has suggested that similar results to bullectomy can be achieved by injecting the patient*s own blood directly into the bulla(e) by bronchoscope. The blood starts an inflammatory reaction which ultimately leads to the formation of scar tissue and shrinking of the treated area. Also, as the clotted blood and inflammatory tissue filling the bulla is slowly absorbed by the body, the walls of the bulla are pulled inwards further shrinking its size. This works to allow expansion of the more healthy lung. If effective, intrabullous autologous blood injection into large bullae can be a readily available, minimally invasive and cheap way of treating large bullae in a group of patients with end-stage disease who have limited treatment options. Currently, 12 patients in Japan and 11 patients in the United Kingdom were treated with this new technique and these studies showed encouraging results, without any serious complications. The encouraging results with using this technique in this patient group and the safety of the procedure has encouraged us to undertake a formal feasibility study to investigate the effectiveness and safety of intrabullous blood instillation.

Study objective

To assess the safety and effects of bronchoscopic intrabullous blood instillation in patients with bullous emphysema on lung function, quality of life measures, functional measures and CT measured lung volumes.

Study design

Prospective open label single arm study.

Intervention

Bronchscopic instillation of autologous blood in the bulla.

Study burden and risks

This study is designed to assess the feasibility and safety of bronchoscopic intrabullous autologous blood instillation for the treatment of severe bullous emphysema. Patients with bullous emphysema will be included who have no other medical treatment, surgical or other experimental bronchoscopic intervention treatment options. It is possible that a patient will not receive any benefits from the treatment. The pilot studies showed promising results on the safety and effects of the procedure. Furthermore, other studies using experimental

bronchoscopic techniques have shown that it is a safe procedure in patients with severe emphysema. The use of autologous blood does not include using foreign implants and is therefore much cheaper. We hope that the procedure will result in the majority of patients in a clinical and statistically significant 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.

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

- Age > 35 years
- Large bulla on CT scan were bullectomy is contraindicated or is actively avoided
- Hyperinflation --> TLC * 100%predcited and RV * 150% predicted

- Exertional breathlessness (mMRC >0)
- Optimum COPD treatment for at least 6 weeks
- No COPD exacerbation for at least 6 weeks
- Fewer than 3 admissions for infective exacerbations in the preceding 12 months
- Written informed consent
- Patients has stopped smoking for a minimum of 6 months prior to entering the study

Exclusion criteria

- Inability to obtain informed consent
- Co-morbidities that would render bronchoscopy or sedation unsafe
- Anaemia or other reasons precluding venesection
- Clinically significant bronchiectasis
- Arrhythmia or cardiovascular disease that poses a risk during procedure
- Lung nodule requiring further investigation or treatment
- Subject taking clopidogrel, warfarin, or other anticoagulants and unable to abstain for 5 days pre-procedure

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2013
Application type:	First submission
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
ClinicalTrials.gov	NCT01727037
CCMO	NL44041.042.13