A multicenter, prospective trial of the Implantable Artificial Bronchus (IAB) in adults suffering from COPD/emphysema

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

Summary

ID

NL-OMON50551

Source
ToetsingOnline

Brief title
IAB-1 study

Condition

- Respiratory disorders NEC

Synonym
COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Pulmair Medical, Inc.
Source(s) of monetary or material Support: Pulmair Medical Inc.

Intervention

Keyword: Bronchoscopy, COPD, Hyperinflation

Outcome measures

Primary outcome

The primary endpoint is the occurrence of respiratory serious adverse events (SAEs), as identified below, through 90 days:

• Acute asthma or bronchospasm requiring admission to an intensive or critical care unit;

• Acute exacerbation of COPD that is acute onset, life-threatening, and requires hospitalization;

• Airway injury from IAB placement, IAB migration, or airway stenosis from an IAB requiring surgical intervention;

• Death from the procedure or device;

• Massive hemoptysis (estimated over 100 ml in 24 hr and requiring transfusion, surgery, or arterial embolization) attributed to the procedure or the device;

• Pneumonia in the IAB-treated lobe that requires hospitalization, IV antibiotics, and IAB removal;

• Pneumonia NOT in the IAB-treated lobe that is life-threatening, acute onset, and requires hospitalization and IV antibiotics;

• Pneumothorax requiring surgical intervention;

• Tension pneumothorax that is life-threatening, acute onset, and requires hospitalization and treatment;

• Respiratory failure that requires mechanical ventilatory support for > 24 hr.

Secondary outcome

There are multiple secondary endpoints:

*Other serious adverse device events (SADEs) are a secondary safety endpoint, to be recorded as they occur regardless of the follow-up schedule.

All efficacy endpoints are secondary, and measured as changes from baseline to 90 days:

• Absolute change in Residual Volume (RV), at both inspiratory and end expiratory levels;

• Percent change in RV (% predicted), at both inspiratory and end expiratory levels, from baseline to endpoint.

• Absolute change in FEV1 from baseline to endpoint.

• Percentage change in FEV1 from baseline to endpoint;

• Absolute change in Six-minute Walk Distance (6MWD);

• Percent change in 6MWD;

• Absolute change in the SGRQ total score;

• Percent change in SGRQ;

• Absolute change in mMRC dyspnea score;

• Absolute changes in COPD Assessment Test (CAT);

• Percent change in CAT Total Score;

• Absolute change in EQ-5D Summary Index;

• Percent change in EQ-5D Summary Index

Study description

Background summary

Patients suffering from severe empysema have limited treatment options. The standard of care is aimed at symptom reduction using (inhaltion)medication and improving exercisice tolerance and disease acceptance. There are two invasive surgical treatments available: lung volume reduction surgery and lung transplantation. However, only a small group of patients is eligable for either one of these treatment options. A, less invasive, alternative is endoscopic lung volume reduction (ELVR). To date, ELVR using one-way valves is the only ELVR treatment option adopted into treatment guidelines and in regular care in the Netherlands. However, this treatment is only effective in patients without contralateral ventilation between the treatment lobe and the ipsilateral lobe. Therefore, other treatment options are developed of which one is the bronchoscopic treatment with the Implantable Artificial Bronchus (IAB). The IAB is a stent which is placed per bronchoscopie in 1 or 2 airways and prevent airway collaps, therefore allowing bidirectional ventilation of the affected lobes with the aim to relieve hyperinflation. This treatment has not been investigated in humans so far.

Study objective

The objective of this trial is to demonstrate a suitable benefit/risk profile to support a subsequent trial of the safety and effectiveness of the IAB to achieve its intended purpose: The IAB is indicated for bronchoscopic treatment of adults with COPD/emphysema to relieve hyperinflation and allow bidirectional ventilation of the affected lobes. The outcome of this trial may inform sample size calculations for a subsequent trial.

Study design

An open-label (unblinded), multicenter, prospective trial of the Implantable Artificial Bronchus (IAB) in adults suffering from COPD/emphysema. There is no control group or comparator.

Intervention

The investigational product is the Pulmair Implantable Artificial Bronchus (IAB). The IABs are placed in the lung by bronchoscope.

Study burden and risks

Patients enrolled in the study will perform baseline testing, including pulmonary function testing (PFT), chest HRCT, blood draw, arterial blood gas, 6 minute walking test (6MWD) and quality of life questionnaires. If a patient fulfils the study criteria, the patient will undergo a bronchoscopic intervention with placement of IAB-stents in the lung. During follow up patients will complete multiple assessments up to 3 year after treatment (PFT, HRCT, 6MWD, arterial blood gas and questionnaires). This will be the first trial in humans investigating this treatment and therefore the risks and benefits of the treatment are unknown. Due to the phenotype of the COPD and emphysema with incomplete fissures there are no other possible regular bronchoscopic interventions at the moment. Patients will only be offered entry into this trial if the consensus decision of the bronchoscopic intervention team 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. Inclusion in the study may lead to improved lung function, exercise tolerability and/or symptom relieve. However, no perceived or measured benefit from this treatment is also possible.

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. Signed Informed Consent
2. Diagnosis of COPD/emphysema
3. Age 40 to 75 years
4. BMI less than 30 kg/m2
5. 6-minute walk Distance between 100 meters and 500 meters at baseline exam
6. Stable disease with less than 10 mg prednisone (or equivalent) daily
7. Non-smoking for 4 months prior to screening interview
8. FEV1 between 15% and 50% of predicted value at baseline exam
9. FEV1/FVC <70%
10. RV > 175%
11. mMRC score >= 2

Exclusion criteria

1. Currently participating in another clinical study
2. Women of child-bearing potential
3. More than 2 COPD exacerbation episodes requiring hospitalization in the last year at screening
4. Any COPD exacerbations within 6 weeks of planned intervention
5. Two or more instances of pneumonia episodes in the last year at screening
6. Clinically significant mucus production or chronic bronchitis
7. Myocardial Infarction or unstable / uncontrolled congestive heart failure within 6 months of screening
8. Prior lung transplant, LVRS, bullectomy or lobectomy
9. Clinically significant bronchiectasis
10. Unable to safely discontinue anti-coagulants or platelet activity inhibitors for 7 days
11. Uncontrolled pulmonary hypertension (systolic pulmonary arterial pressure >45 mm Hg) or evidence or history of cor pulmonale as determined by recent echocardiogram (completed within the last 3 months prior to screening visit)
12. Suspected pulmonary nodule or lung cancer
13. HRCT collected per CT scanning protocol within the last 6 months of screening date and evaluated by clinical site personnel using 3D segmentation software shows:
a. Large bullae encompassing greater than 30% of either lung

b. Insufficient landmarks to evaluate the CT study using the software as it is intended
c. All lobes are less than 25% parenchyma diseased (< -950 HU)
14. Any cardiac comorbidity which the PI believes would compromise the safety of the patient after an IAB implant
15. TLC < 100% predicted at screening
16. DLCO < 15% or > 50% of predicted value at screening
17. PaCO2 > 50 mm Hg or Denver scale greater than 55 mm Hg on room air at screening
18. PaO2 < 45 mm Hg or Denver scale less than 30 mm Hg on room air at screening
19. Plasma cotinine level > 13.7 ng/ml or arterial carboxyhemoglobin >2.5% at screening
20. Any other conditions, which, in the opinion of the Investigator, would make the patient unsuitable for inclusion, or could interfere

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Implantable Artificial Bronchus (IAB)
Registration:	No

Ethics review

Approved WMO Date:	01-04-2022
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	NCT05087641
CCMO	NL78836.000.21