Bronchoscopic Release of Air Trapped in Hyperinflated Emphysematous Lung

Published: 26-07-2023
Last updated: 19-08-2024

Primary safety objective: The primary safety objective of the study is to assess the safety of the Apreo Endobronchial System for treatment of severe emphysema.

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

Summary

ID

NL-OMON56894

Source
ToetsingOnline

Brief title
BREATHE-2 study

Condition

- Respiratory disorders NEC

Synonym
COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Medical Devices company - Apreo Health Inc.
Source(s) of monetary or material Support: Medical Devices company - Apreo Health Inc.

Intervention

Keyword: Airtrapping, COPD, emphysema, Medical device

Outcome measures

Primary outcome

Assessment of the rate of occurrence of serious adverse events (SAE) related to the device and/or study procedure through 6 months post-Apreo Procedure #1.

Secondary outcome

Feasibility endpoints include: • Evaluation of ability to deploy the Apreo Implant in target airways • Evaluate operator device use challenges • Evaluation of operator understanding of instructions for use Preliminary efficacy endpoints include: • Implant obstruction assessed bronchoscopically in the proximal, medial and distal thirds at 3- and 6--month visits using a semi-quantitative scale (0-5) with 0 representing no narrowing within the lumen of the implant, 1: 1% - 10%, 2: >10% - 25%, 3: >25% - 50%, 4: >50% - 75%, 5: >75% - 100%. • Mucous within the Apreo Implant assessed bronchoscopically in the proximal, medial and distal thirds at 3- and 6--month visits using a semi-quantitative scale with 0: No mucous within the lumen of the implant, 1: Minimal, 2: Mild, 3: Moderate, 4: Severe, 5: Copious. • CT assessment of Apreo Implant diameter in mm at the middle of the implant, 5 mm proximal to the distal end and 5 mm distal to the proximal end at 6- and 12-month visits • Change in the following at 1-3 days, 30 days, and 3, 6, and 12 months post-Apreo Procedure #1 relative to baseline: o FEV1 o RV assessed by pulmonary function testing o RV/TLC o FVC o FEV1/FVC o Exercise capacity (6MWD) o SGRQ-C Score o CAT Score o mBORG Scores o mMRC Score • Change in DLCO at 6 months

post-Apreo Procedure #1 relative to baseline • Change in RV assessed by quantitative CT analysis at 6 and 12 months post-Apreo Procedure #1 relative to baseline • ABG parameters: PaO2 and PaCO2 at 6 months post-Apreo Procedure #1 relative to baseline Secondary Safety Endpoints • Percentage of participants with acute procedural complications (within 24 hours of an Apreo Procedure • Rates of occurrence of serious adverse events (SAE) related to the device and/or Apreo Procedure through 24 months post-Apreo Procedure #1 • Rates of adverse device effects through 24 months post-Apreo Procedure #1

Study description

Background summary

Emphysema is a lung condition that causes shortness of breath. In people with emphysema, the air sacs in the lungs (alveoli) are damaged. Over time, the inner walls of the air sacs weaken and rupture, creating larger air spaces instead of many small spaces. This larger air space reduces the air sac wall elasticity and reduces the amount of oxygen that reaches the bloodstream. When you exhale, the damaged alveoli do not work properly and old air becomes trapped, leaving no room for fresh, oxygen-rich air to enter. The trapped air can cause the lungs to overinflate (hyperinflation).

The Apreo Endobronchial System is made up of the Apreo Implant and Apreo Delivery System.

The Apreo Implant is an investigational implant that is a metal tube that acts like a scaffold to hold open your airways in your lungs, and the Apreo Delivery System is an investigational catheter that is used to place the Apreo Implant in the lung airway.

Study objective

Primary safety objective: The primary safety objective of the study is to assess the safety of the Apreo Endobronchial System for treatment of severe emphysema.

Study design

First-in-human, prospective, multi-center, single-arm study

Intervention

Implantation of the Apreo Endobronchial Implant into the affected lung(s).

Study burden and risks

Subjects will be required to visit the hospital for the procedures and follow-up visits, where they will complete questionnaires and undergo tests (listed in detail in the previous part of this form) multiple times during the study. The procedure(s) will require 1-3 days hospitalization.

There are potential risks associated with the Apreo Endobronchial System, as listed in section 2.3.4 of the protocol. There may also be risks that are unanticipated at this time. The Apreo Endobronchial System was designed to minimize unacceptable and/or unnecessary risk. While some residual risks remain, these residual risks are considered acceptable when accounting for the potential benefits of increasing pulmonary function, exercise capacity, and quality of life for patients who suffer from severe emphysema.

The protocol is designed to minimize risk to potential participants through careful selection of appropriate participants, robust study procedures, follow-up and ongoing safety surveillance. Based on the risk analysis and risk minimization strategies described above, the potential risks to participants are outweighed by the potential benefits.

Contacts

Public
Medical Devices company - Apreo Health Inc.

4040 Campbell Ave 110
Menlo Park, CA CA 94025
US
Scientific
Medical Devices company - Apreo Health Inc.

4040 Campbell Ave 110
Menlo Park, CA CA 94025
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >= 35 and <= 80 years old 2. Computed tomography (CT) scan evidence of homogeneous or heterogeneous emphysema 3. At least one target lobe with > 35% destruction (percent of voxels with < -950 Hounsfield units on CT) 4. Post-bronchodilator ratio of FEV1/FVC < 0.7 at screening 5. Post-bronchodilator FEV1 percent predicted >=15% and <=50% of predicted at screening 6. Post-bronchodilator RV > 180% predicted 7. Post-bronchodilator RV/TLC >= 0.55 at screening 8. Marked dyspnea, scoring >= 2 on the modified Medical Research Council scale of 0-4 9. Cotinine testing at screening indicates nonsmoker and stopped smoking at least 8 weeks before entering the trial and agrees to refrain from smoking for duration of study participation 10. Fully vaccinated for Covid-19 and has current pneumococcus and influenza vaccination (or documented clinical intolerance) 11. Cognitively and physically able to provide written informed consent and complete participant questionnaires

Exclusion criteria

1. Arterial blood PaCO2 > 60 mmHg (8 kPa) or PaO2 <= 45 mmHg (6 kPa) 2. DCLO <20% at screening 3. Steroid therapy of 10 mg prednisolone (prednisone) or more per day 4. Three or more acute exacerbations of COPD in the past year before enrollment 5. Two or more hospitalizations for acute exacerbations of COPD or respiratory infections in the past year before enrollment 6. Any acute exacerbation of COPD or respiratory infection less than 4 weeks before the first Apreo Procedure 7. Previous lung volume reduction surgery or lobectomy, segmentectomy or bullectomy, vapor, glue, or other pulmonary device implant 8. Known history of pulmonary arterial hypertension 9. Presence of a giant bulla (>= 30% of hemithorax) 10. History of excessive dynamic airway collapse of the trachea or main bronchi 11. History of adult asthma or chronic bronchitis 12.

Presence of suspicious pulmonary nodule/infiltrate that requires additional follow-up, diagnostics or treatment 13. Unequivocal and symptomatic bronchiectasis 14. Unequivocal lung cancer or other current cancer diagnosis except non-metastasized basal cell skin cancer 15. Uncontrolled hypertension (blood pressure that is inadequately treated or resistant to treatment) with a systolic > 200 mmHg or diastolic > 110 mmHg at screening or prior to first Apreo Procedure 16. Uncorrectable coagulopathy or other condition likely to increase risk of peri- or post- Apreo Procedure bleeding 17. On anticoagulant or antiplatelet therapy and unable or unwilling to hold for Apreo Procedure 18. Coronary artery disease with angina 19. History of myocardial infarction within 6 months 20. History of a stroke less than 1 year before the first Apreo Procedure 21. Clinical history of heart failure with documented LVEF <= 40% 22. Clinical history of diabetes with a HbA1c > 9.0% 23. Estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m2 (CKD-EPI) OR participant with kidney failure (Stage 5 kidney disease)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-07-2023
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Apreo Endobronchial System
Registration:	No

Ethics review

Approved WMO Date:	26-07-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-07-2024
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

No registrations found.

In other registers

Register	ID
Other	ClinicalTrials.gov Identifier: NCT05854550
CCMO	NL84373.000.23