Targeted lung denervation (TLD) with the Ryme Medical Lung Denervation System in patients with chronic obstructive pulmonary disease (COPD)

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Primary ObjectiveThe primary objective of the study is to evaluate the safety of The Ryme Medical Lung Denervation System.Secondary ObjectivesThe secondary objective of the study is to evaluate the performance of The Ryme Medical Lung Denervation...

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

Summary

ID

NL-OMON57123

Source
ToetsingOnline

Brief title
Ryme Medical TLD Pilot Study

Condition

- Respiratory disorders NEC

Synonym
chronic obstructive pulmonary disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Ryme Medical

Source(s) of monetary or material Support: Ryme Medical

Intervention

Keyword: chronic obstructive pulmonary disease, Lung Denervation System, Ryme Medical

Outcome measures

Primary outcome

The primary safety analysis will be the assessment of incidence and

characterization of any serious adverse events associated with the Ryme Lung

Denervation System through 30 days.

Secondary outcome

The analysis of device performance will be the assessment of:

• Device Success:

Successful delivery and retrieval of the catheter

• Technical Success:

Device success with the ability to deliver cryoablation to each intended

location

Device performance will be assessed at the completion of the Index Procedure.

Study description

Background summary

This research is an Early Feasibility Study of a non-surgical procedure called targeted lung denervation (TLD) using a new, experimental device.
The experimental device is called the Ryme Medical Lung Denervation System, manufactured by a company called Ryme Medical, Inc. in Mountain View,

California, USA. This research is being conducted by and is sponsored by Ryme Medical.

With COPD there are nerves within the lungs that potentially overreact to irritation (e.g., allergens such as pollution, infections). When the nerves overreact, they can cause the airways to narrow and cause the lungs to create more than normal amounts of mucus making it more difficult to breathe and causing COPD flare-ups.

The TLD procedure with the Ryme Medical Lung Denervation System is designed to reduce this airway nerve activity, which may potentially reduce how often a patient with COPD has COPD flare-ups or reduce how severe the symptoms become. The TLD procedure uses cryoablation (freezing temperatures) to *inactivate* specific nerve branches in the airway that are believed to contribute to COPD flare-ups.

The Ryme Medical Lung Denervation System has undergone extensive bench-top testing and has been successfully used in pigs and sheep, which have similar lung structures to humans.

Study objective

Primary Objective

The primary objective of the study is to evaluate the safety of The Ryme Medical Lung Denervation System.

Secondary Objectives

The secondary objective of the study is to evaluate the performance of The Ryme Medical Lung Denervation System.

Study design

The study is a prospective, multi-center, non-randomized, single-arm study to evaluate the safety and performance of The Ryme Medical Lung Denervation System in patients with chronic obstructive pulmonary disease (COPD).

Intervention

TLD procedure with the Ryme Medical Lung Denervation System

Study burden and risks

Potential Risks of the Study Procedure and Investigational Device

The risks associated with bronchoscopy and general anesthesia are the predominant risks of the study. The majority of the risks of the investigational TLD procedure are similar to the risks of bronchoscopy as noted in Table 6-1. The likelihood of these risks is unknown, but the frequency is expected to be similar to bronchoscopy.
Potential risks associated the study device and the TLD procedure may include but are not limited to those outlined in Table 6-2. The likelihood of these risks is anticipated to be rare, but the actual rates are unknown, as this is the initial introduction of the investigational Ryme Medical Lung Denervation System into a human population. However, bench-top testing and animal studies have demonstrated that the TLD procedure can be performed safely and reliably. The Ryme Medical Lung Denervation System performed as intended in both the porcine and ovine models. Bench testing and animal studies of the system have demonstrated adequate safety at extended chronic timepoints and performance to provide justification and confidence to transition to the next phase of clinical testing via human clinical studies. Refer to the Investigator Brochure for additional information.
There may be other unknown complications that may occur as a result of this procedure. If these or any of the above complications occur, they may lead to repeat or prolonged hospitalization, repeat procedures, emergency surgery, other emergency procedures, or in rare cases, death. The study doctor and/or his research staff will make every effort to minimize additional risks.

Potential Benefits
Patients who are eligible for this study suffer from moderate or severe COPD and are highly symptomatic. A participant may benefit from the TLD procedure. The potential benefits include a reduction of COPD symptoms such as reduced cough, reduced sputum production, reduced breathlessness and/or reduced or less frequent exacerbations. Patients may also experience other possible health improvements and/or symptom relief associated with that reduced symptom burden of COPD such as improvement in quality of life and/or functional improvement such as increased exercise endurance.
Other benefits of participation in this study are altruistic and are related to the knowledge and information that will be obtained to further the design and development of The Ryme Medical Lung Denervation System and treatment of COPD.

Risk Management
All efforts will be made to minimize the identified risks by taking the following measures:
• Investigational sites will be confirmed to have adequate resources, staff and facilities to perform the procedures as outlined in the schedule of assessments
• Investigators will be physicians who have training and experience in performing bronchoscopic procedures. Investigators will be trained in proper procedure performance and device operations prior to patient treatment
• Defined study protocol, including specific inclusion/exclusion criteria to enroll appropriate patients in the study
• Ongoing monitoring of study data and results

Risk-Benefit Rationale
This pilot study will enroll patients with moderate or severe COPD with significant symptom burden with limited relief from available treatment options. These high-risk patients have limited treatment options and are at high risk of morbidity and mortality. The non-surgical, minimally invasive, TLD procedure may provide symptom relief or mediate disease progresses providing an adjunct therapy for patients suffering from COPD.

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. Patient has diagnosis of chronic obstructive pulmonary disease with post-bronchodilator FEV1/FVC of < 70% of predicted and FEV1 >=30% and < 80%
2. Patient has symptomatic COPD, despite treatment with established best

guideline directed medical therapy, demonstrated by an mMRC grade >= 2 or CAT score >= 10
3. Patient is >=40 years of age at the time of enrollment
4. Patient has a smoking history of at least 10 pack years, and/or has significant environmental exposure equivalent in the opinion of the investigator
5. Patient has provided written informed consent
6. Patient is willing and able to comply with the study protocol
7. Patient is a candidate for bronchoscopy in the opinion of the Investigator

Exclusion criteria

1. Patient has anatomy precluding proper device delivery or function and/or high likelihood of incomplete treatment
2. Patient has had recent COPD exacerbation, or respiratory infection, within 6 weeks of screening or is currently taking antibiotics and/or steroids for treatment of an exacerbation
3. Patient has undergone prior lung intervention with device currently implanted, and/or had administration of therapeutic cryo or radio frequency (RF) in the airway
4. Patient has asthma as defined by the current Global Initiative for Asthma (GINA) guidelines
5. Patient has history of mycobacterium avium complex (MAC) lung infection requiring treatment
6. Patient has other non-COPD lung disease or condition affecting the lungs such as bronchiectasis, allergic bronchopulmonary aspergillosis, interstitial lung disease, or active tuberculosis (or currently receiving treatment for tuberculosis)
7. Patient has pulmonary nodule or cavity that in the opinion of the Investigator may require intervention during the course of study participation
8. Patient has malignancy requiring treatment, is actively receiving chemotherapy or radiation therapy and/or has received treatment within 6 months of screening
9. Patient is using any tobacco products, using e-cigarettes, vaping or using other inhaled non-pharmacological substance
10. Patient has documented history of myocardial infarction, cerebrovascular accident, or transient ischemic attack within 6 months of screening
11. Patient has left ventricular ejection fraction <= 45%
12. Patient has clinically significant serious or unstable medical conditions (e.g., uncontrolled diabetes or hypertension)
13. Patient has known contraindication or allergy (that cannot be medical controlled) to any of the following: medications required for bronchoscopy; general anesthesia; or materials comprising the patient contacting portion of the device
14. Patient is unable or unwilling to discontinue antiplatelet or anticoagulant therapy for the index procedure

15. Patient has any other condition, in the opinion of the Investigator, that may interfere with study follow-up or completion
16. Patient is currently enrolled in another clinical study that has not completed follow-up
17. Patient is pregnant, nursing, or intent to become pregnant during study participation

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):	13-08-2024
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Ryme medical lung denervation system
Registration:	No

Ethics review

Approved WMO

Date:	01-07-2024
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	NCT05967091
CCMO	NL85849.042.24