

Evaluating the Safety and Efficacy of dNerva Lung Denervation System in Patients With COPD

Status: RECRUITING

Eligibility Criteria

Age: 40 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* ≥ 40 and ≤ 80 years of age at the time of consent. * Women of childbearing potential must not be pregnant, evidenced by a negative pregnancy test (blood or urine) pre-treatment, or lactating and agree not to become pregnant for the duration of the study. * Smoking history of at least 10 pack years. * Not smoking or using any other inhaled substance (e.g. cigarettes, vaping, cannabis, pipes) for a minimum of 2 months prior to consent and agrees to not start for the duration of the study. * Resting SpO₂ $\geq 89\%$ on room air. * MMRC ≥ 2 ; CAT score ≥ 10 . * Diagnosis of moderate to severe COPD as defined by FEV₁/FVC $< 70\%$ (post-bronchodilator), $25\% \leq$ FEV₁ $\leq 70\%$ predicted, and PaCO₂ < 50 (if FEV₁ $< 30\%$). * RV $\geq 175\%$ of predicted and RV/TLC $> 55\%$ (post-bronchodilator). * Participant is on standard medical care, defined as a minimum of therapy with LABA/ICS, LAMA/LABA, or LAMA/LABA/ICS for at least 2 months prior to consent. * If subject has participated in a formal pulmonary rehabilitation program recently, program completion must have occurred ≥ 3 months prior to consent; if in a maintenance program, subject agrees to continue their current program through their 12-month follow-up visit; NOTE: Prior participation in a pulmonary rehabilitation program is not required for inclusion in the study. * Participant is a candidate for bronchoscopy in the opinion of the investigator or per hospital guidelines and is able to discontinue blood thinning medication peri-procedurally. * Participant is able and agrees to complete all protocol required baseline and follow up tests and assessments including taking certain medications (e.g., azithromycin, prednisolone/prednisone).

Exclusion Criteria:

* Body Mass Index (BMI) < 18 or > 32 . * Participant has an implantable electronic device and has not received appropriate medical clearance. * Uncontrolled diabetes in the opinion of the investigator. * 4 or more respiratory related hospitalizations within 1 year of consent. * Malignancy treated with radiation or chemotherapy within 1 year of consent. * Participant diagnosed with a dominant non-COPD lung disease, or condition affecting the lungs, which is the main driver of the participant's clinical symptoms (e.g., cystic fibrosis, paradoxical vocal cord motion, eosinophilic granulomatosis with polyangiitis (EGPA), allergic bronchopulmonary aspergillosis, interstitial lung disease or active tuberculosis or Asthma) or has a documented medical history of pneumothorax within 1 year of consent. * Clinically relevant bronchiectasis, defined as $> 1/3$ cup mucous expectoration daily. * Pre-existing diagnosis of pulmonary hypertension, clinical evidence of pulmonary hypertension (e.g., cardiovascular function impairment including peripheral edema) and mPAP ≥ 25 mmHg at rest by right heart catheterization (or estimated right ventricular systolic pressure > 50 mmHg by echocardiogram if no previous right heart catheterization). * Myocardial infarction within last 6 months, evidence of life-threatening arrhythmias or acute ischemia, pre-existing documented evidence of a LVEF $< 40\%$, stage C or D (ACC/AHA) or Class III or IV (NYHA) congestive heart failure. * Surgical procedure(s) on the stomach, esophagus or pancreas performed ≤ 2 years of consent, or ongoing related symptoms within the past year. * Symptomatic gastric motility disorder(s) (e.g., gastroparesis) as evidenced by GCSI score ≥ 18.0 , severe uncontrolled GERD (e.g., refractory heartburn, endoscopic esophagitis) or severe dysphagia (e.g., esophageal stricture, achalasia, esophageal spasm). NOTE: Participants with a hiatal hernia are allowed if Participant meets all other enrollment criteria. * Any disease or condition that might interfere with completion of a procedure or this study (e.g., structural esophageal disorder, life expectancy < 3 years). * Prior lung or chest procedure (e.g., BLVR explant procedure, median sternotomy, bullectomy, lobectomy, segmentectomy or other interventional lung or chest procedure) performed ≤ 1 year of consent? Participants with lung transplant, BLVR valves, LVRS, metal stents within 5cm of the anticipated treatment location; presence of lung volume reduction valves, coils or other lung implants. * Daily use of > 20 mg of prednisone or its equivalent at the time of consent. * Known contraindication or allergy to medications required for bronchoscopy or general anesthesia (e.g., lidocaine, atropine, propofol, sevoflurane) that cannot be medically controlled. * Baseline chest CT scan reveals bronchial anatomy cannot be treated with available catheter sizes; presence of whole lung emphysema $> 20\%$ (> 950 HU), single lung emphysema $> 26\%$ (> 950 HU), severe bullous disease ($> 1/3$ hemithorax) or discovery of a mass that requires treatment. * Participant is currently enrolled in another drug or interventional clinical trial that has not completed follow-up.

Conditions & Interventions

Interventions:

DEVICE: Targeted Lung Denervation (TLD)

Conditions:

COPD, Chronic Obstructive Pulmonary Disease

Keywords:

Optimal Medical Care, Device: dNerva Lung Denervation System, Device: Targeted Lung Denervation (TLD)

More Information

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IRB

Number:

System ID: NCT07051707

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