Clinical Study of the RheOx Bronchial Rheoplasty System in Treating the Symptoms of Chronic Bronchitis

Status: Recruiting

Eligibility Criteria

Age: 35 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Patient is at least 35 years of age. 2. Patient has chronic bronchitis, defined as productive cough for three months in each of two successive years, whereas other causes of productive cough have been ruled out. 3. Patient has a CAT score ≥ 10. 4. Patient has an SGRQ score ≥ 25. 5. Patient's responses to the first two questions of the CAT instrument sum to ≥ 7 points or the sum is 6 points and the patient's total CAT score is > 20 points. 6. Patient has FEV1/FVC < 0.70. 7. Patient has a pre-procedure post-bronchodilator FEV1 percent predicted of ≥ 30%. 8. Patient is receiving guideline directed pharmacotherapy which includes one or more long acting bronchodilator (LAMA, LABA) with or without an inhaled corticosteroid for at least 8 weeks prior to randomization, unless the patient has attempted such therapy within the past 1 year without significant clinical response or had an adverse reaction. 9. Patient has a cigarette smoking history of at least ten pack years. 10. In the opinion of the Primary investigator, patient is able to undergo 2 bronchoscopies under general anesthesia and is able to adhere to the study follow-up schedule

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Exclusion Criteria:

1. Patient has known unresolved lower respiratory tract infection (e.g., pneumonia, mycobacterium avium-intracellulare infection (MAI), fungus, tuberculosis). 2. Patient has a steroid-dependent condition requiring >10 mg of oral corticosteroid per day. 3. Patient has any implantable electronic device (e.g., pacemaker, cardioverter defibrillator) that cannot be turned off during the procedure. 4. Patient has a history of ventricular tachy-arrhythmia or clinically significant atrial tachyarrhythmia within the past two years, unless the arrhythmia has been treated and/or patient is in regular rhythm during the screening phase. 5. Patient has unresolved lung cancer. 6. Patient has a pulmonary nodule or cavity that in the judgement of the Primary investigator may require intervention during the course of the study. 7. Patient had prior lung surgery, such as lung transplant, LVRS, lobectomy, lung implant/prosthesis, metal airway stent, valves, coils or bullectomy. Prior pneumothorax without lung resection, pleural procedures without surgery, or segmentectomy are acceptable. 8. Patient has emphysema of greater than or equal to 25% as quantified on baseline HRCT scan (low attenuation area less than -950HU) as determined by the CT Core Lab. 9. Patient has asthma based on Global Initiative for Asthma (GINA) criteria. 10. Patient has clinically significant bronchiectasis influencing the patient's clinical symptoms of cough and phlegm. 11. Patient has actively smoked (including tobacco, marijuana, e-cigarettes, vaping, etc.) within the last 6 months. 12. Patient is unable to walk over 225 meters in 6 minutes. 13. Patient has a serious medical condition that, in the Primary investigator's opinion, could compromise patient safety or confound the interpretation of the patient's response to therapy (e.g., congestive heart failure, cardiomyopathy, or myocardial infarction in the past year, renal failure, liver disease cerebrovascular accident within the past 6 months, uncontrolled diabetes (HbA1c >8%), uncontrolled hypertension (diastolic BP >100mmHg) or autoimmune disease requiring treatment with immunosuppressant medications or a disease requiring chemotherapy). 14. Patient has uncontrolled GERD. 15. Patient has known severe pulmonary hypertension. 16. Patient has a known sensitivity to medication required to perform bronchoscopy (i.e., lidocaine, atropine, benzodiazepines). 17. Patient is pregnant, nursing, or planning to get pregnant during study duration. 18. Patient is currently participating in another clinical study involving an investigational product

Conditions & Interventions

Interventions:
Device: RheOx Bronchial Rheoplasty, Device: Sham Procedure
Conditions:
Chronic Bronchitis
Keywords:
COPD

More Information

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Phase: N/A
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System ID: NCT04677465
