RheSolve Clinical Study

for previous smokers with Chronic Bronchitis

RheOx™ Bronchial Rheoplasty

Below are several key criteria to consider when speaking with prospective patients. If you feel your patient may be a good candidate, provide them with the website address below. The QR code provided below will take prospective patients directly to the website. Here they will fill out a short survey and if the prospective patient meets initial criteria, he/she will be referred to the local study site.

Inclusion Criteria

- Chronic Bronchitis defined clinically as a productive cough for three months in two successive years
- Ambulatory former smokers with at least a 10-pack year smoking history
- Patient is receiving guideline directed medical therapy (i.e., LABA, LAMA, with or without ICS)
- Has not actively smoked in the last 6 months
- Sum of COPD Assessment Test (CAT) Q1 and Q2 (cough and mucus score) ≥ 6
- Baseline post-bronchodilator $FEV_1/FVC < 0.7$
- Baseline post-bronchodilator FEV_1 percent predicted of $\geq 30\%$

Exclusion Criteria

- Implanted electronic devices (i.e., pacemaker, ICD, neuro-stimulation devices)
- History of arrhythmia within past two years which includes tachy-atrial arrhythmias, any ventricular tachy-arrhythmias, or sinus bradycardia with heart rate less than 45 bpm
- Other predominant disease states that may mimic the clinical presentation of chronic bronchitis producing cough and mucus such as clinically significant bronchiectasis, uncontrolled GERD, chronic rhinosinusitis, asthma, etc.
- Other serious medical condition including CHF, cardiomyopathy, certain autoimmune disorders, etc.
- Prior lung surgery, airway stent(s), valves, coils, or other lung implant/prothesis
- Prior severe respiratory infection with SARS-CoV-2 (COVID-19) that required ICU support with non-invasive and/or invasive mechanical ventilation
- Known nickel allergy

Refer potential patients to www.BronchitisStudy.com to see if they qualify

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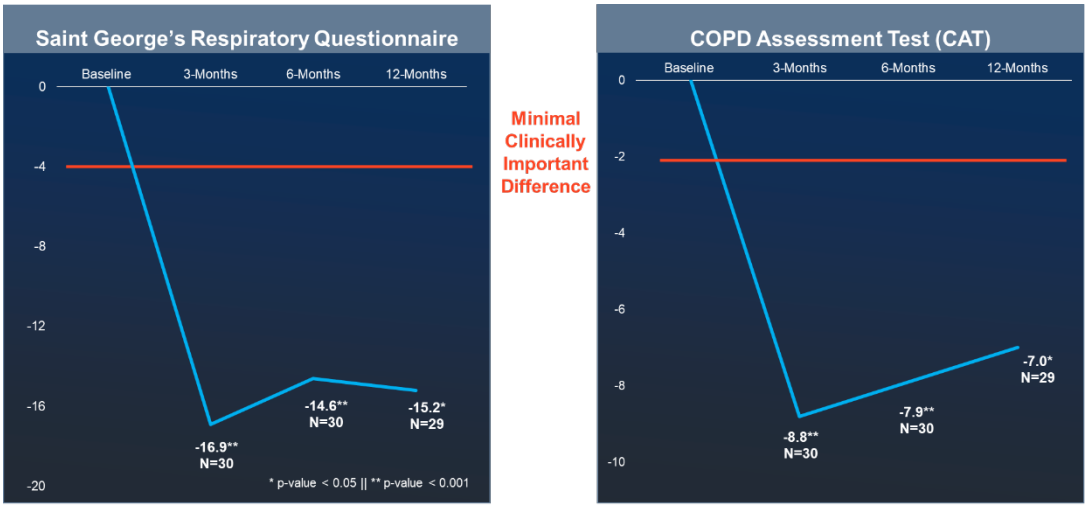
Previous Studies

RheOx, an investigational device in the US and approved in Europe (CE Mark), has been studied in several clinical trials. Results from a 30-patient study published in the American Journal of Respiratory and Critical Care Medicine, demonstrated[1]:

- Safe and well-tolerated procedure with no device-related serious adverse events.
- Significant reduction in airway goblet cell hyperplasia ($p<0.002$).
- Clinically meaningful improvements in patient quality of life at 12 months, based on a 15.2-point mean reduction ($p=0.0003$) in St. George's Respiratory Questionnaire (SGRQ) and a 7.0-point mean reduction ($p=0.0008$) in COPD Assessment Test (CAT).

Improvement in Quality of Life Outcomes



RheSolve Study

The RheOx RheSolve Trial is a double-blind, randomized, sham controlled study in COPD patients with moderate to severe chronic bronchitis. The trial is assessing the safety and efficacy of the RheOx System when used to treat the symptoms of chronic bronchitis. The primary efficacy endpoint is the change from baseline to 6 months in the COPD Assessment Test (CAT) score.

A total of 270 patients will be randomized in a 2:1 ratio to treatment or sham procedure at up to 40 US centers and up to 10 international centers. Patients will undergo the minimally invasive procedure in two sessions, approximately one month apart, and will then be followed for 24 months with just 3 in-person follow-up visits required. Patients in the control group will have the option to cross-over after 12 months.

www.BronchitisStudy.com

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[1] A. Valipour, et al. Bronchial Rheoplasty for Treatment of Chronic Bronchitis: 12 Month Results from a Multi-Center Study. Am J Respir Crit Care Med 2020. https://www.atsjournals.org/doi/pdf/10.1164/rccm.201908-1546OC