

The RheSolve Clinical Study

Frequently Asked Questions



If you're living with **Chronic Bronchitis** still experience symptoms despite your medications, you may qualify for the RheSolve Clinical Study. The study is for Bronchial Rheoplasty using RheOx™, an investigational device designed to reduce cough and mucus production through a minimally-invasive procedure.

1. What is the purpose of a clinical study?

Clinical studies (also called clinical trials) are used to learn about the safety and effectiveness of new medications, medical devices, and medical procedures. Although there are many types of clinical trials, all must conform to strict rules set by each country's regulatory authorities. These rules help protect the rights and safety of those who volunteer to take part in clinical trials.

2. Where is the study being conducted?

The RheSolve Study is being conducted at up to 40 study centers in the US, Canada, and Europe.

3. How is RheOx designed to work?

RheOx is designed to reduce cough and mucus production through a non-surgical procedure. The procedure is performed through a bronchoscope, a thin flexible tube that is inserted through the mouth into the lungs.

Once in place, RheOx delivers short bursts of electrical energy to the inner walls of the bronchi, eliminating the mucus-producing cells. Over the next several days, new cells grow and produce less mucus. The right lung is treated first, followed by treatment of the left lung about 1 month later.

4. Has RheOx been used before?

Yes, RheOx has been used in previous clinical trials in the US, Canada, Europe, Australia, and South America. Your local study team can share these results with you.

5. How long does the study last?

The study lasts about 2 years, and involves up to 6 in-person visits to your local study center. Some of the visits are treatment visits, while others are follow-up visits to evaluate your progress. You will be compensated for your time and travel to attend these visits.

6. Does everyone in the study receive the RheOx treatment?

Yes, this study is a "randomized" study which means some participants will receive their RheOx treatment right away, while others will receive a simulated or "sham" treatment, in which no energy is delivered. The decision as to which treatment you initially receive is decided at random, like picking from a hat. Initially, 67% of participants will receive the RheOx treatment, while 33% will receive the sham treatment. Participants will not be told which treatment they initially received.

However after the 12-month follow-up visit, if you were in the sham group, and your doctor feels treatment with RheOx is appropriate, you will be offered the option to receive the RheOx procedure at no cost, and your study doctor will continue to monitor your progress.

7. Will I have to pay for anything if I choose to join the RheSolve Study?

No, if you qualify and choose to join the RheSolve Study, you will receive the RheOx treatment and all study-related care and follow-up visits at no cost.

8. What if I join the study and decide I do not want to participate anymore?

As with all clinical studies, your participation is completely voluntary and you may leave the study at any time without any effect on your future medical care.

9. I am interested in possibly moving forward. What is the next step?

Please contact your local study center, and they will work with you to schedule a convenient time for your initial visit.

Thank you for your interest in our study. Please do not hesitate to contact us with any questions!