

Aerify COPD Clinical Research Study



Why participate in a clinical research study?

Millions of people enroll in clinical research studies every year. The reasons why people choose to join are as unique and varied as the people themselves. A clinical research study may offer them choices when current treatments are not as helpful as hoped/expected.

Some people enroll to help potentially find a future treatment or for science. The reasons why you consider a clinical research study are yours alone. You should only decide once you have learned all about a clinical research study.

If you decide to enroll in this study, you will be seeing the study doctor regularly. For someone with COPD, participating in this clinical research study can be helpful BUT because some participants will receive placebo, benefit is not guaranteed. What is IMPORTANT is that your current medications will NOT be stopped and either the study drug or placebo will be added on top.

Do you qualify for this study?

You may be eligible if you:

- Are at least 40 to 85 years of age
- Are diagnosed with COPD for at least a year
- Are a current or former smoker
- Are currently taking the required medications

It's okay if you don't know if you qualify, the study doctor will tell you if you do.

For more information on this clinical research study or to see if you may qualify or participate

Contact Us:
United Memorial Medical Center
Cesar Barrera or Greg Lyons
cbarrera@ummc.care or glyons@lfros.com
Phone: (281) 513-3360 or (832) 659-4042
or contact us at
research@lfros.com
www.lfrosresearch.com



A clinical research study for adults with moderate to severe chronic obstructive disease (COPD), currently being treated with established inhalers that have a combination of two or three medications.

What is COPD?

COPD is a chronic condition of the lungs, mainly caused by smoking along with environmental air pollution, that causes the patient to have trouble breathing even for routine activities of daily living. It results in progressive airflow obstruction that is mostly irreversible but also may be partly reversible with medications. The disease is further aggravated by exacerbations, particularly for severe COPD. According to the World Health Organization (WHO) estimates, 65 million people have moderate to severe COPD worldwide. While there is no cure for COPD, symptoms can typically be improved/controlled to an extent.



What is the Aerify COPD Study?

The Aerify COPD clinical research study is being conducted by respiratory disease doctors to determine if the study medication can reduce the rate of moderate to severe acute exacerbations or sudden worsening of COPD. The study will gather this information over 1 year of treatment.

The study medication (one not yet approved by the health authority) called itepekimab is an injectable medication as opposed to the most used COPD medications which are inhalers. The clinical research study will also evaluate if the study medication helps to improve the way patients feel and breathe, as well as their level of activity, which may potentially reduce the need for rescue or reliever medications.

Patients on this study will receive either itepekimab or placebo. Placebo is an inactive solution that does not contain medication. Study medications and/or placebo will be injected under the skin ("subcutaneously") once every 2 weeks. For former smokers, you will have a 1 in 3 chance and for current smokers, you will have a 1 in 2 (or 50%) chance of receiving placebo only, on this study. You will NOT stop your regular controller/rescue medications (inhalers) and either itepekimab or placebo will be added on top.

This study is for people who have moderate to severe COPD and are currently being treated with standard of care therapy. This therapy must include LABA + LAMA or LABA + inhaled corticosteroid treatment (Duel therapy) OR LAMA + LABA + inhaled corticosteroid therapy (Triple Therapy).

Common examples of these medications would be fluticasone propionate as an inhaled corticosteroid, salmeterol as a LABA and tiotropium as a LAMA, though there are several others. If you are taking this treatment for at least 3 months, you may qualify for this study. The study doctor/site will be able to tell you whether or not you are taking the required medication.

If you enroll in this study, you may receive study-related medical examinations, investigational and routine COPD medications and compensation for time and travel, where permitted. Also, if you enroll, you will be seen by a doctor who will closely watch your COPD.

What are Clinical Research Studies?

Clinical research studies are used to show if/how a study medication works and to find out if it is safe. They can also be referred to as clinical research trials. Qualified doctors run clinical research studies. The doctors are responsible for the study-related care of the people that participate (or enroll) in these studies.

Independent committees (called Institutional Review Boards or IRBs) made up of medical and nonmedical people who also watch over clinical research studies to make sure that the people who enroll are told everything they need to know and that they are protected.

