

What is a clinical trial?

A clinical trial is a scientific study in which participants are assigned to one or more investigational drugs to answer questions about the treatment to see if it works, works better than other treatments, and has side effects.

What is an investigational drug?

An investigational drug is a substance that is being tested in clinical trials. It has been approved by an ethics committee for testing in people and may or may not be approved by the government health agency for treatment for this condition.

Why should I take part in this study?

Clinical trials or studies are important for medical advances. Current treatments for diseases are only available because of research study volunteers.

Thank you for your interest in the ECLIPSE research study for adults with chronic rhinosinusitis with nasal polyposis.

For more information, please contact:

There's a science to the art of breathing free.

And it begins with research.

The ECLIPSE study is researching treatment for adults with chronic rhinosinusitis with nasal polyposis.

Protocol number: ANB020-006



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Why is this study important?

If you have chronic rhinosinusitis with nasal polyposis (CRSwNP), you probably know that nasal polyps can cause congestion, runny nose, pain or pressure in your face, and/or a reduced sense of smell. You may have used other treatments or had surgery to try to control these uncomfortable symptoms. However, nasal polyps usually come back—even after other treatments or surgery. Some people with nasal polyps may need longer lasting control.

Pharmaceutical companies use clinical research studies like this one to learn more about investigational medications before they are made available to the public. Study volunteers can help us in this important research. Thank you for considering participation in this trial.

What is the purpose of this study?

The purpose of this clinical trial is to test the safety and effectiveness of the study drug, etokimab.

The study drug (etokimab or placebo) will be given by subcutaneous injection every 4 weeks for 4 months. A placebo looks like the test medicine but contains no active ingredients (medicine). Subcutaneous injections are given just under the skin into a layer of body fat (the tummy or upper arms).

Who can participate in this study?

To be eligible for this study, you must:

- Be 18 to 70 years of age
- Have nasal polyps in both nostrils
- Have at least 2 of the following symptoms:
 - Nasal blockade/obstruction
 - Nasal congestion
 - Nasal discharge (anterior/posterior nasal drip)
 - Facial pain/pressure
 - Reduction or loss of smell
- Be a non-smoker
- Sign the informed consent form

This is not a complete list of eligibility criteria. The study doctor will review the full criteria for this study with you.

How long will the study last?

Your participation in this study will last approximately 28 weeks (7 months start to finish) and you will come to the study center for about 9 visits. There is a possibility you may need to return for additional visits if your study doctor believes it is necessary.

What can I expect if I decide to participate?

There are 3 dosing groups receiving different doses of study drug. You will be assigned randomly (like the flip of a coin) to one of the 3 dosing groups. You have a greater than 50% chance of being in one for the active treatment groups.

This is a blinded study, which means neither you nor the study doctor will know to which of these study groups you are assigned. In case of an emergency; however, the study doctor can get this information.

Lab tests, a physical exam, and other assessments will be conducted at the in-clinic visits. Not all activities will occur at every visit.

What are the benefits and costs if I take part in this study?

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge. You will be reimbursed for reasonable and acceptable study-related travel costs.

What risks are involved if I decide to participate?

Any study has risks, which may include things that could make you feel uncomfortable, ill, or in rare situations harm you. You might experience side effects related to the study drug while participating in the study. All participants in the study will be watched carefully for any side effects; however, the study team does not know all the effects that the study product(s) may have on you.

The study team may give you medicines to help reduce side effects. These side effects may be mild or serious. In some cases, these side effects might be long-lasting, or permanent, and may even be life-threatening.

In previous studies, the study drug was generally safe and well-tolerated. Some mild to moderate symptoms were experienced by participants, such as:

- upper respiratory tract infection (common cold)
- headache
- abdominal pain
- nausea
- vomiting
- rash
- tiredness

A condition called cytokine release syndrome may also occur, with symptoms such as:

- Mild to moderate fever, chills, headache, nausea, and vomiting
- Moderate to severe symptoms such as swelling of the skin, low blood pressure, and blood and mucus in the lungs