ForPatients
by Roche

Chronic Obstructive Pulmonary Disease (COPD)

A clinical trial to see how well different doses of astegolimab plus standard treatment work compared with a placebo plus standard treatment to reduce certain symptoms of chronic obstructive pulmonary disease

A Study to Evaluate Astegolimab in Participants With Chronic Obstructive Pulmonary Disease

Trial Status	Trial Runs In	Trial Identifier
Recruiting	37 Countries	NCT05595642 GB44332

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will evaluate the efficacy and safety of astegolimab compared with placebo in participants with chronic obstructive pulmonary disease (COPD) who are former or current smokers and have a history of frequent exacerbations.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT05595642 GB44332
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=40 Years & <= 80 Years	No

1. Why is the ARNASA clinical trial needed?

Chronic obstructive pulmonary disease (COPD) is a group of conditions that affect the airways of the lungs, causing narrowing of the airways, which limits airflow in and out. COPD causes symptoms such as breathlessness and cough, often with increased mucus production.

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Standard treatments for COPD include inhalers of corticosteroids and bronchodilators, and symptoms can often be improved with lifestyle changes, such as stopping smoking and doing physical activities. However, COPD is a progressive disease, which means that it gets worse over time. Some people experience episodes when their symptoms flare up (also known as 'COPD exacerbations'). Mild COPD exacerbations may be managed by increasing the amount of standard treatment. Still, additional treatment with corticosteroids and/or antibiotics at home or in hospital may be required for moderate and severe COPD exacerbations. Having COPD exacerbations more often can affect how well the lungs work and is linked to a worsening quality of life. Better treatments are needed to help prevent COPD from getting worse and reduce the number of COPD exacerbations.

COPD exacerbations can be triggered by viral infections, allergies, or irritants (such as chemicals or dust) which damage cells that line the airways of the lungs and cause them to release a protein called interleukin-33 (IL-33). IL-33 helps the body's immune system to fight infections. However, in people with COPD, it can cause too much inflammation that affects the airways. This makes breathing more difficult and causes extra mucus production. Astegolimab is a type of drug called a monoclonal antibody that acts to block the activities of IL-33 and may be effective at reducing the number of COPD exacerbations. Astegolimab is an experimental drug, meaning health authorities have not approved astegolimab for treating COPD.

In this clinical trial, researchers will assess if people with COPD have fewer moderate or severe COPD exacerbations when astegolimab (at one of two doses) is added to their standard COPD treatment.

2. How does the ARNASA clinical trial work?

This clinical trial is recruiting people who have a health condition called COPD. People can take part if they smoke or used to smoke cigarettes and have experienced at least two moderate or severe COPD exacerbations in the past year.

The purpose of this clinical trial is to compare the effects, good or bad, of astegolimab against placebo in people with COPD. People who take part in this clinical trial will receive either astegolimab and/or a placebo, as well as their usual COPD medications as prescribed by their doctor.

Participants will be given the clinical trial treatment astegolimab or placebo for about 1 year. Participants will be seen by a member of the clinical trial team every 2 weeks. These visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. Participants will have a follow-up visit 3 months after being given the final dose of clinical trial treatment, and their total time in the clinical trial will be about 1 year and 3 months (62 weeks). Participants are free to stop trial treatment

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and leave the clinical trial at any time. After finishing treatment in this trial, participants may be given the opportunity to be given astegolimab treatment in a separate trial.

3. What are the main endpoints of the ARNASA clinical trial?

The main clinical trial endpoint is the result that is measured in the trial to see if the medicine has worked. In this trial, the main endpoint is the number of moderate and severe COPD exacerbations while treatment is being given.

Other clinical trial endpoints help to understand better how the treatment affected participants. For this trial, they include:

How much time passes from the start of the trial to participants having moderate or severe COPD exacerbations

Change from the start of the trial in:

o health-related quality of life (how much COPD affects everyday activities)

o respiratory symptoms (such as shortness of breath), and

o the amount of air that participants can forcibly breathe out

Number and seriousness of any side effects.

4. Who can take part in this clinical trial?

People can take part in this trial if they are aged 40–80 years and have been receiving certain treatments for COPD for a minimum of 1 year. Participants must also be former or current cigarette smokers who have had two or more moderate or severe COPD exacerbations in the past year. All participants must be able to complete an electronic diary as part of the trial.

People may not be able to take part in this trial if they have certain other medical conditions, such as asthma, or have previously received certain treatments, including lung transplant or treatment with astegolimab. Women who are pregnant or breastfeeding or are planning to become pregnant will not be able to take part in this trial.

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5. What treatment will participants be given in this clinical trial?

This is a ‘placebo-controlled’ clinical trial, which means some people will be given a substance with no active ingredients (also known as a ‘placebo’) which looks like the drug being tested. Comparing results from the different groups helps the researchers know whether any changes seen are a result of the drug or if they are occurring by chance.

Everyone who joins this clinical trial will be split randomly into three groups (with an equal chance of being in any group) and will be given either:

Group 1: Astegolimab given as two injections under the skin (known as a subcutaneous injection) every 2 weeks for 50 weeks

OR

Group 2: Either astegolimab or placebo alternating every 2 weeks (so that astegolimab is given every 4 weeks), given as two injections under the skin (known as a subcutaneous injection) for 50 weeks

OR

Group 3: Placebo given as two injections under the skin (known as a subcutaneous injection) every 2 weeks for 50 weeks

This is a double-blind trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This approach helps to prevent bias and expectations about what will happen. However, the participant’s clinical trial doctor can find out which group the participant is in, if their safety is at risk.

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What does the ARNASA clinical trial look like?

1. Can I take part in this clinical trial?

If the trial is still open to new patients, your doctor will run tests to see if the clinical trial is suitable for you

If you have COPD, smoke or used to smoke cigarettes, have had two or more COPD exacerbations in the past year and the clinical trial is suitable for you, your doctor will explain the clinical trial and the rights that you have so you can decide if you want to take part

If you want to take part, you will be entered into one of three different treatment groups randomly (with an equal chance of being in any group)

2. What treatment will I be given?

Group 1

1 in 3 chance of being given **astegolimab** as two injections under the skin (subcutaneous injection) every 2 weeks for 50 weeks

Group 2

1 in 3 chance of being given either **astegolimab** every 2 weeks or **placebo** every 2 weeks (so that astegolimab is given every 4 weeks), each given as two injections under the skin (subcutaneous injection) for 50 weeks

Group 3

1 in 3 chance of being given **placebo** as two injections under the skin (subcutaneous injection) every 2 weeks for 50 weeks

3. What happens during the clinical trial?

You will be seen by a member of the clinical trial team every 2 weeks to see how you are responding to the treatment and any side effects you may be having

Your total time in the clinical trial will be about 1 year and 3 months (62 weeks)

After finishing treatment in this trial, you may be given the opportunity to be given astegolimab treatment in a separate trial

You can leave the clinical trial at any time and you will not lose access to your regular care

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6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe and even life-threatening and can vary from person to person.

Astegolimab

Potential participants will be told about the known side effects of astegolimab and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

Astegolimab and placebo will be given as two injections under the skin (known as subcutaneous injections). Participants will be told about any known side effects of being given subcutaneous injections.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT05595642

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