ForPatients
by Roche

Asthma

A clinical trial to compare the safety and effectiveness of selnoflast with a placebo and understand how the body processes selnoflast in people with moderate to severe asthma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	5 Countries	2023-504304-29-00 BP44551

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A phase Ib, multicenter, randomized, placebo-controlled, double-blind study to evaluate the safety, pharmacokinetics and pharmacodynamics of selnoflast in participants with moderate to severe asthma

Trial Summary:

A clinical trial to compare the safety and effectiveness of selnoflast with a placebo and understand how the body processes selnoflast in people with moderate to severe asthma

F.Hoffmann-La Roche Ltd.
Sponsor

Phase 1
Phase

2023-504304-29-00 BP44551
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 80 years	No

1. Why is the BP44551 clinical trial needed?

Asthma is a common long-term lung condition caused by swelling (inflammation) of the airways that causes occasional breathing difficulties. Inflammation is the body's normal reaction (immune response) to an injury, infection, or irritation – in people with asthma, the body overreacts. The current standard treatment for asthma is inhaled corticosteroids (ICS) and bronchodilators (medications that open the airways); however, many people have uncontrolled symptoms and asthma attacks (exacerbations), and

new treatments are needed. The body produces a protein called NLRP3 that can amplify the immune response and inflammation. A drug called selnoflast blocks the activity of NLRP3 and could reduce inflammation in the lungs of people with asthma. Selnoflast is an experimental drug, which means that health authorities (like the U.S. Food and Drug Administration, Health Canada, Medicines and Healthcare products Regulatory Agency, and European Medicines Agency) have not approved selnoflast for the treatment of asthma. Selnoflast has been tested in healthy people and in people with ulcerative colitis in other studies, and is being tested in people with Parkinson's disease and coronary artery disease.

This clinical trial aims to compare what happens to selnoflast once it is in the body, and what selnoflast does to the body and your disease when compared with placebo – a substance which looks like a drug but has no active ingredient – in people with asthma.

2. How does the BP44551 clinical trial work?

This clinical trial is recruiting people with moderate to severe asthma (determined by the amount and type of treatment people receive). People who take part in this clinical trial (participants) will be given the clinical trial treatment selnoflast OR placebo for 6 weeks, in addition to their usual asthma medication. The clinical trial doctor will see them every 1–2 weeks. These clinic visits will include checks to see how the participant responds to the treatment and any side effects they may have (visits 4 and 6 may take place at home, although home visits may not be available to all participants). The total time of participation in the clinical trial will be about 11 weeks including follow-up. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the BP44551 clinical trial?

The main clinical trial endpoint (the main results measured in the trial to see if the drug has worked) is the number, type, and seriousness of any side effects.

The other clinical trial endpoints include how the body processes and reacts to selnoflast, and measurements that see if selnoflast improves people's breathing and quality of life.

4. Who can take part in this clinical trial?

People can take part in this trial if they are 18–80 years old and have been diagnosed with asthma for at least 1 year. People must also:

- Be taking certain treatments for asthma for at least 3 months, including an ICS and a long-acting (effects last at least 12 hours) bronchodilator
- Have not smoked for at least 6 months
- Provide a sputum (also known as phlegm – a thick type of mucus made in your lung) sample by coughing

People may not be able to take part in this trial if they:

- Have certain lung or other health conditions, or have had cancer in the last 5 years
- Are pregnant or breastfeeding

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

Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin) and given either:

- Selnoflast OR placebo capsule to be taken orally (swallowed) twice a day for 6 weeks

Participants will have an equal chance of being placed in either group. Over the 6-week treatment period all participants will receive placebo for at least 2 weeks during the study. Participants will also continue their usual asthma medication throughout the study. This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given a substance with no active ingredients (also known as a 'placebo'); it looks like the drug being tested but does not contain any real medicine. Comparing results from the different groups helps the researchers know whether any changes seen result from the drug or occur by chance. This is a double-blinded 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 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.

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. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate 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. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial treatment

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly. Participants will be told about the known side effects of selnoflast, and possible side effects based on human and laboratory studies or knowledge of similar drugs. Selnoflast and placebo will be given as oral capsules. Participants will be told about any known side effects of swallowing

capsules and will be informed how to take the study medication. Participants will have the opportunity to discuss any concerns they may have about the clinical trial and its treatment.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future. Participants will be informed about the results of the clinical trial in due course.

Inclusion Criteria:

- Documented physician-diagnosed asthma for at least 12 months prior to Screening.
- Treatment with non-biologic asthma controller therapy for #3 months prior to screening and no changes in controller dosing regimens within 4 weeks prior to screening or during the screening period, or anticipated need for changes throughout the study.
- Morning pre-bronchodilator forced expiratory volume in 1 second (FEV1) of 40% - 90% of predicted at screening.
- Demonstrated post-bronchodilator reversibility of FEV1 #12% and #200 millilitres (mL) at Screening, or at least one documented historic evidence of lung function variability within 5 years prior to screening
- Non-smoker or former smoker. A former smoker is defined as someone with smoking history who has not used inhaled tobacco or cannabis products within 6 months prior to Screening. Current smoking is not permitted.
- Asthma Control Questionnaire, 5-item version (ACQ-5) score #1.5 at screening
- hs-CRP #1 milligrams per liter (mg/L) at screening.
- Body mass index (BMI) within the range of 18 - 40 kilograms per square meter (kg/m2) (inclusive).
- Ability to provide an adequate sputum sample

Exclusion Criteria:

- History of malignancy within 5 years prior to screening.
- History of any clinically significant hepatic disease or cirrhosis.
- Known immunodeficiency including, but not limited to, human immunodeficiency virus (HIV) infection.
- Respiratory infection (including upper respiratory and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections) within 2 weeks prior to screening or during the Screening period.
- Other infection requiring oral or intravenous (IV) antibiotics, antivirals, or antimycotics within 2 weeks prior to screening or during the Screening period.
- History of tuberculosis or a positive Interferon-Gamma Release Assay (IGRA) test at screening.
- Presence of hepatitis B surface antigen (HBsAg) at Screening or within 3 months prior to dosing.
- Positive hepatitis C (HCV) antibody test result at Screening or within 3 months prior to starting study treatment.
- Vaccine(s) within 4 weeks prior to Screening