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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

Submission date 07/09/2023	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 22/09/2023	**Overall study status** Ongoing	
Last Edited 04/04/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

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 the disease when compared with placebo – which looks like a drug but has no active ingredient – in people with asthma.

Who can participate?

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 (slow-release) bronchodilator
- Have not smoked for at least 6 months
- Provide sputum (also known as phlegm – a thick type of mucus made in the 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

What does the study involve?
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.

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 a 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.

What are the possible benefits and risks of participating?
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).

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.

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.

Where is the study run from?
F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?
July 2023 to November 2025

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
global.trial_information@roche.com

Study website
https://forpatients.roche.com/en/trials/respiratory-disorder/asthma/a-clinical-trial-to-compare-the-safety-and-effectiveness-of-seln.html

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2023-504304-29-00

IRAS number
1008183

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BP44551, IRAS 1008183, CPMS 57069

Study information

Scientific 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

Acronym
BP44551 Asthma Study

Study objectives
The main purpose of this study is to evaluate the safety of selnoflast as compared to placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/10/2023, Conjoint Health Research Ethics Board (2500 University St NW, Calgary, Alberta, T2N 1N4, Canada; +1 403-220-2297; chreb@ucalgary.ca), ref: REB23-0815

Study design
Phase I multicenter randomized placebo-controlled double-blind study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home, Hospital

Study type(s)
Treatment, Safety

Participant information sheet

Health condition(s) or problem(s) studied
Moderate to severe asthma

Interventions
Participants will be randomly divided in the following two treatment groups by using the interactive voice/web response system (IxRS):

1. Selnoflast: Participants will receive selnoflast capsules, orally, twice daily (BID) for about 4 weeks during the 6-week treatment period
2. Placebo: Participants will receive selnoflast matching placebo capsules, orally, BID for about 6 weeks

Over the 6-week treatment period all participants will receive placebo for at least 2 weeks during the study.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

Phase
Phase I

Drug/device/biological/vaccine name(s)
Selnoflast

Primary outcome measure
Current primary outcome measure as of 30/09/2024:
1. Number of participants with adverse events (AEs), and severity of AEs assessed according to National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0 (NCI CTCAE v5.0) from placebo-run baseline up to Day 43

Previous primary outcome measure:
1. Number of participants with adverse events (AEs), and severity of AEs assessed according to National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0 (NCI CTCAE v5.0) from placebo-run period (day -14) up to day 43

Secondary outcome measures
1. Plasma concentration of selnoflast, measured by specific and validated liquid chromatography with tandem mass spectrometry (LC-MS/MS) Method, From Day 1 up to Day 43
2. Change in high sensitivity C-Reactive Protein (hs-CRP), assessed using the blood samples collected from baseline to Day 29

Overall study start date
10/07/2023

Completion date
12/11/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/09/2024:
1. Documented physician-diagnosed asthma for at least 12 months prior to Screening.
2. 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.
3. Morning pre-bronchodilator forced expiratory volume in 1 second (FEV1) of 40% - 90% of predicted at screening.
4. 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
5. 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.
6. Asthma Control Questionnaire, 5-item version (ACQ-5) score ≥1.5 at screening
7. hs-CRP ≥1 milligrams per liter (mg/L) at screening.

8. Body mass index (BMI) within the range of 18 - 40 kilograms per square meter (kg/m2) (inclusive).
9. Ability to provide an adequate sputum sample

Previous inclusion criteria:
1. Documented physician-diagnosed asthma for at least 12 months prior to Screening.
2. 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.
3. Morning pre-bronchodilator forced expiratory volume in 1 second (FEV1) of 40% - 90% of predicted at screening.
4. Demonstrated post-bronchodilator reversibility of FEV1 ≥12% and ≥200 millilitres (mL) at Screening, or documented historical reversibility of FEV1 ≥12% and ≥200 mL within 5 years prior to screening
5. No history of smoking or former smoker with smoking history of < 20 pack-years or equivalent history.
6. Asthma Control Questionnaire, 5-item version (ACQ-5) score ≥1.5 at screening
7. hs-CRP ≥2 milligrams per liter (mg/L) at screening.
8. Body mass index (BMI) within the range of 18 - 40 kilograms per square meter (kg/m2) (inclusive).
9. Ability to provide an adequate sputum sample

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
60-90

Key exclusion criteria
Current exclusion criteria as of 30/09/2024:
1. History of malignancy within 5 years prior to screening.
2. History of any clinically significant hepatic disease or cirrhosis.
3. Known immunodeficiency including, but not limited to, human immunodeficiency virus (HIV) infection.
4. 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.
5. Other infection requiring oral or intravenous (IV) antibiotics, antivirals, or antimycotics within 2 weeks prior to screening or during the Screening period.

6. History of tuberculosis or a positive Interferon-Gamma Release Assay (IGRA) test at screening.
7. Presence of hepatitis B surface antigen (HBsAg) at Screening or within 3 months prior to dosing.
8. Positive hepatitis C (HCV) antibody test result at Screening or within 3 months prior to starting study treatment.
9. Vaccine(s) within 4 weeks prior to Screening

Previous exclusion criteria:
1. History of malignancy within 5 years prior to screening.
2. History of any clinically significant hepatic disease or cirrhosis.
3. Known immunodeficiency including, but not limited to, human immunodeficiency virus (HIV) infection.
4. Respiratory infection (including upper respiratory and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections) within 6 weeks prior to screening.
5. Other infection requiring oral or intravenous (IV) antibiotics, antivirals, or antimycotics within 2 weeks prior to screening
6. History of tuberculosis or a positive Interferon-Gamma Release Assay (IGRA) test.
7. Presence of hepatitis B surface antigen (HBsAg) at Screening or within 3 months prior to dosing.
8. Positive hepatitis C (HCV) antibody test result at Screening or within 3 months prior to starting study treatment.
9. Vaccine(s) within 4 weeks prior to Screening

Date of first enrolment
04/04/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Belgium

Canada

England

Germany

Netherlands

United Kingdom

Study participating centre
Medicines Evaluation Unit Ltd.
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Study participating centre
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Sponsor information

Organisation
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Sponsor type
Industry

Website
http://www.roche.com/about/

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
12/11/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available