Summary of Clinical Study Results for Participants

A study to look at the safety of selnoflast (RO7486967) in people with early Parkinson's disease, how it moves through the body and the effects it has

Definitions of key medical terms can be found at the end of this summary in the Glossary.

Title of the Study:	A Phase 1b, adaptive, multi-center, randomized, double blind, placebo-controlled, parallel design study to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of RO7486967 in participants with early idiopathic Parkinson's disease
Protocol Number:	BP43176
Study Identifier:	2023-504412-14-00 (EU CT) and NCT05924243 (ClinicalTrials.gov)
Medicine(s) Studied:	**Selnoflast** (also known as 'RO7486967')
Study Start and End Date:	September 27, 2022 to July 18, 2024
Date of Summary:	September 02, 2025
Status of This Study:	This summary was written after the study ended and includes an analysis of all the data collected throughout the study.
Disease Studied:	This study involved people with **Parkinson's disease** with no known cause. This is also known as 'idiopathic Parkinson's disease'.
Type of Study:	This study is a Phase 1b, randomised, double-blind, placebo-controlled study of selnoflast. Phase 1b is an important step in the research process where a treatment is tested in a small number of people. The purpose of this phase is to see how safe the treatment is and how it moves through the body. In a double-blind study, nobody knows which treatment is being given – not the people in the study or the team running it. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. 'Randomised, placebo-controlled' means that people are put in a group that gets given a medicine or a group that gets given a non-active medicine (placebo). People are placed into groups by chance, like flipping a coin. Each group may receive a different treatment, and this helps researchers compare and see which treatment works better than others

Thank you to our participants

We would like to thank all the individuals who took part in this study and their families, as well as carers who support their participation.

Study participants belong to a large community of individuals around the world who have made it possible for researchers to answer important health questions and discover new medicines. We hope you feel proud of the critical role you play in medical research.

As the company that has organised and funded this research, we believe it is important for you, and people like you, to know the results of this study. If you have questions about the information in this summary, please speak with the doctor or nurse at the clinic where you participated in the study.

It is important to note that the information presented in this summary is from one study. Remember that one study cannot tell us everything about the possible effects of a study medicine and how well it may or may not work. It takes a lot of people, participating in many studies to learn as much as we can about new medicines. This is why the results of this study may be different from the results of other studies of the same medicine.

Why was this study needed?

Parkinson's disease (PD) is a long-term condition that gets worse over time. In PD, a naturally occurring protein called alpha-synuclein does not form properly. It sticks together to form clumps. This damages nerve cells in certain areas of the brain and causes nerve cells to die. Some of these nerve cells are responsible for the production of a chemical called 'dopamine', which is important for controlling movement. The damage to nerve cells leads to a lack of dopamine in the brain causing movement-related (motor) and non-motor symptoms.

Symptoms include tremors, poor balance, feeling tired or weak, and a persistent feeling of sadness and loss of interest that can affect daily functioning. Current treatments can help with symptoms but don't stop the disease from getting worse. Medicines like levodopa replace dopamine, while others help the brain use or keep dopamine for longer. As the disease gets worse, these medicines become less effective at controlling symptoms. New medicines are needed that can prevent brain cell death to stop or slow the speed at which PD gets worse.

Some research suggests that inflammation in the brain may play a role in PD and how it worsens. A protein called NLRP3 is thought to be a key part of this inflammation.

This study looked at a medicine called selnoflast. It is being developed to block NLRP3, a protein that may affect the brain's immune system and help reduce inflammation. This could slow the the speed at which PD gets worse. Selnoflast is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved it for the treatment of PD. This study compared the effects of selnoflast against non-active medicine (placebo) in people with PD.

What was the main purpose of the study? What did researchers want to find out?

Researchers did this study to find out how safe selnoflast was, which they measured by counting how many people had unwanted effects when taking the medicine during the study and how severe these effects were.

The main question researchers were trying to answer was how many participants had unwanted effects, and how serious were they?

Other questions researchers want to answer were:

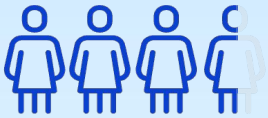
- Does selnoflast reach NLRP3 in the brain of people with early PD, as shown by changes in brain scans before and after treatment?

Who took part in the study?

57 people with
PD of no known cause

At 21 centres

In the Netherlands,
the United Kingdom and
the United States



39% were women

61% were men

People could join the study if they were taking
PD medicines for symptom control if the dose had not
changed for at least 1 month

Participants were between 45
and 81 years of age

Additionally, people had:

- To have been diagnosed with PD between 3 months and 5 years previously
- To be able to swallow pills whole
- To be a healthy weight with a body mass index of 18 to 32 kg/m^2

The following people could not take part in this study:

- People with another Parkinsonian syndrome, dementia or central nervous system disorder such as stroke
- People with a psychiatric condition such as major depression or schizophrenia
- People who had had brain surgery for PD
- People who were pregnant or breastfeeding

What medicines were used in this study?

Research suggests that inflammation in the brain may play a role in PD and how it worsens. A protein called NLRP3 is thought to be a key part of this inflammation. Selnoflast is a small molecule that blocks a protein called NLRP3, which is involved in inflammation.

Selnoflast

Selnoflast blocks a protein called NLRP3.

This may help reduce brain inflammation and slow down the speed at which PD gets worse.

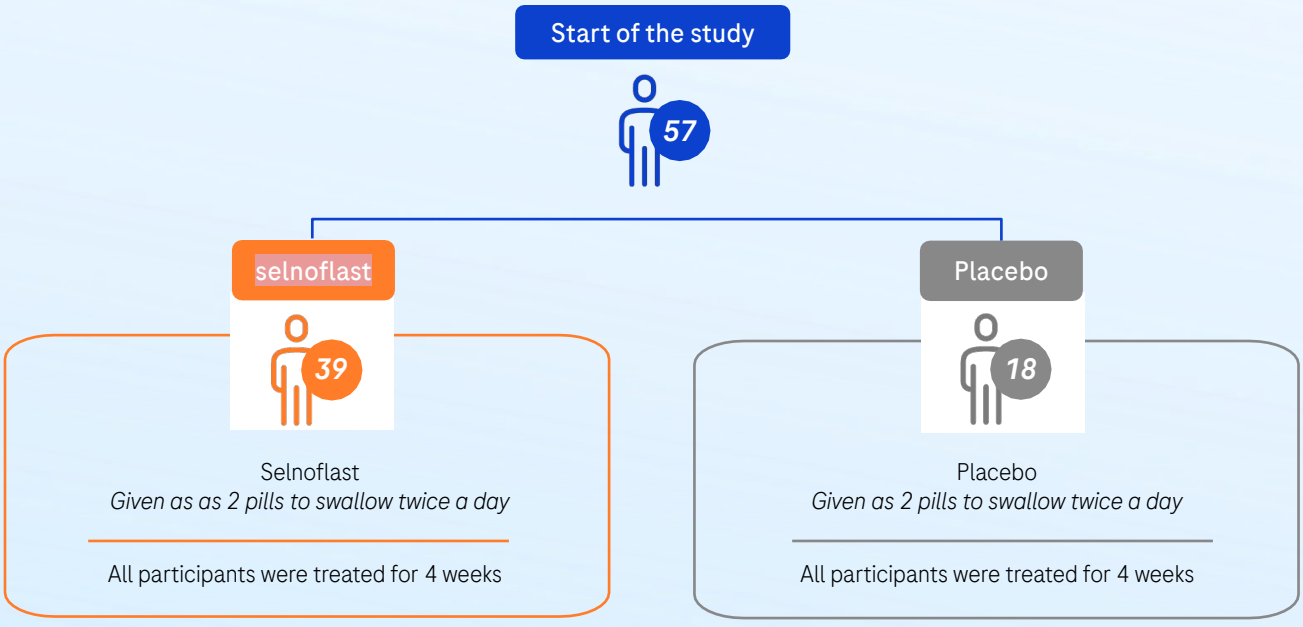
Placebo

A medicine that contains no active ingredients but looks the same and is taken the same way as the study drug. This means that it does not have any medicine-related effect on the body.

How was the study conducted?

Everyone who joined this study was first split into 2 groups randomly (like flipping a coin) and given either selnoflast or placebo as pills to swallow. There was a 2 in 3 chance of being given selnoflast and 1 in 3 chance of being given placebo.

All participants had a positron emission tomography (PET) scan – a type of imaging test – to check for signs of inflammation in their brain before and after treatment (Day 25).



What were the results of the study?

1. How many participants had unwanted effects, and how serious were they?

Unwanted effects (also called "adverse reactions") are medical problems that happen during a study. They are described in this summary because the study doctor believes the unwanted effects were related to the study medicine used in the study. Unwanted effects may be mild to very serious and can be different for each person. Not all the people in this study experienced all the unwanted effects noted below.

Common unwanted effects are those that are experienced by at least 1 in every 10 participants (10% of participants). Mild unwanted effects are medical problems that do not impact a participant's daily routine. Moderate unwanted effects are those that are not life threatening, but that may impact a participant's day-to-day life. In these cases, the participant may need to have their study medicine dose adjusted or may need additional treatment. Serious unwanted effects are those that may result in death, may require a participant to be hospitalised, or may extend a participant's time in hospital.

In this study, selnoflast was given twice a day for 28 days:

- It was well tolerated across all 39 participants
- No one experienced serious unwanted effects and no new unwanted effects were found
- There were no deaths

2. What unwanted effects did the participants experience?

In this study, researchers looked at the safety of **selnoflast** compared with placebo by measuring the number and type of unwanted effects experienced by all the people who participated in the study. The tables below show **all** the unwanted effects that were thought to be **related** to the study medicine, and how often they happened during the study.

Selnoflast	
Effect	Number of participants impacted
All unwanted effects (including mild and moderate effects)	
Pain or discomfort in the head (headache)	2 out of 39 (5%)
Feeling tired or weak (fatigue)	0 out of 39 (0%)
Throwing up (vomiting)	0 out of 39 (0%)
Wanting to throw up (nausea)	1 out of 39 (3%)
Higher than usual ALT levels in the blood	0 out of 39 (0%)
A low number of red blood cells (anaemia)	0 out of 39 (0%)
Dizziness	0 out of 39 (0%)
Feeling generally sick or unwell (malaise)	0 out of 39 (0%)
Higher than usual C-reactive protein	0 out of 39 (0%)
Infection due to the presence of a virus in the body	0 out of 39 (0%)
Passing wind (flatulence)	1 out of 39 (3%)
Problem that affects the digestive system (gastrointestinal disorder)	1 out of 39 (3%)

Placebo	
Effect	Number of participants impacted
All unwanted effects (including mild and moderate effects)	
Pain or discomfort in the head (headache)	4 out of 18 (22%)
Feeling tired or weak (fatigue)	2 out of 18 (11%)
Throwing up (vomiting)	2 out of 18 (11%)
Wanting to throw up (nausea)	1 out of 18 (6%)
Higher than usual ALT levels in the blood	1 out of 18 (6%)
A low number of red blood cells (anaemia)	1 out of 18 (6%)
Dizziness	1 out of 18 (6%)
Feeling generally sick or unwell (malaise)	1 out of 18 (6%)
Higher than usual C-reactive protein	1 out of 18 (6%)
Infection due to the presence of a virus in the body	1 out of 18 (6%)
Passing wind (flatulence)	0 out of 18 (0%)
Problem that affects the digestive system (gastrointestinal disorder)	0 out of 18 (0%)

What were the results of the study?

3. Does selnoflast reach NLRP3 in the brain of people with early PD?

In this study, researchers wanted to find out if selnoflast reaches the brain and interacts with a protein called NLRP3, which is linked to inflammation in PD. To find out, researchers used images of the brain from PET and Magnetic Resonance Imaging (MRI) scans before treatment and again on Day 25.

Researchers found:

- A difference in the level of a marker that appears in higher amounts when there is inflammation in the brain between people who took selnoflast (the study treatment) and those that took placebo – this means that selnoflast reached its target in the brain
- That selnoflast interacts with the NLRP3 protein in the brain

Future studies will find out what this effect means for the long-term symptoms and worsening of PD.

How has this study helped research?

This study showed that selnoflast reaches the NLRP3 protein in the brain of people with early PD, as seen through changes in brain scan markers.

The study also showed that selnoflast was well tolerated. There were no serious unwanted effects, and all other unwanted effects had been seen in previous clinical studies – no new safety concerns were found.

Where can I find more information about this study?

More information about this study can be found on the ForPatients website at:

A Study to Investigate The Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of RO7486967 in Participants With Early Idiopathic Parkinson's Disease Learn about the purpose, design, and participant information on the Roche ForPatients site.

BP43176– ClinicalTrials.gov Explore official registration details, eligibility criteria, and study updates.

What other studies are being conducted for this medicine?

At the time of writing this summary, further studies are planned for medicines that block NLRP3 in people with PD.

Sponsor(s):

This study was paid for and conducted by F. Hoffmann-La Roche Ltd (Roche).

Contact details:

If you have any further questions after reading this summary, please visit ForPatients.Roche.com and click on the 'Talk to us' link at the top of the page.

If you took part in this study and have questions about the results, please speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment, please speak with the doctor in charge of your treatment.

Glossary of key medical terms

Alpha-synuclein: a naturally-occurring protein that sticks together to form clumps in people with PD. This damages nerve cells in the brain and causes nerve cells to die, affecting a person's movement and other functions

Brain immune activity: how the brain's own immune cells respond to damage or disease. In PD, these cells can become more active, which may lead to inflammation. Scientists measure this activity to understand how treatments like selnoflast might be working in the brain

Dopamine: a chemical produced by the body which is important for controlling movement and happiness

Double-blind: a type of study where nobody knows which treatment is being given – not the people in the study or the team running it. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment

Idiopathic Parkinson's disease (PD): a condition with no known cause and symptoms such as slowed movements, stiffness, and tremors

Immune cells: group of cells in the body that help protect a person from germs and keep a person healthy

Levodopa: a medicine used to treat the symptoms of PD. It replaces dopamine in the body

Motor symptoms: movement-related symptoms

MRI scan: a Magnetic Resonance Imaging scan is a detailed picture of the inside of the body taken with a special machine

PET scan: a Positron Emission Tomography scan is a type of imaging test

Phase 1b: is an important step in the research process where a treatment is tested in a small number of people. The purpose of this phase is to see how safe the treatment

Placebo: a medicine that contains no active ingredients but looks the same and is taken the same way as the study medicine. This means that it does not have any medicine-related effect on the body

Proteins: large, complex molecules that play many critical roles in the body. They do most of the work in cells and form almost everything in the body, from hair and skin to cells

Putamen: area of the brain linked to movement

Randomised- controlled study: a study where people are placed into groups by chance, like flipping a coin. Each group may receive a different treatment, and this helps researchers compare and see which treatment works better than others

Selnoflast: the medicine tested in this study