ForPatients
by Roche

Chronic Obstructive Pulmonary Disease (COPD)

A study to assess the safety of RO7486967 in patients with chronic obstructive pulmonary disease

Phase Ib, randomized, double-blind, placebo-controlled, parallel-group study to assess the safety of RO7486967 in patients with chronic obstructive pulmonary disease

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	BP43098

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 is a research study (also known as a clinical trial) of a drug called RO7486967. RO7486967 is being developed for the possible treatment of chronic obstructive pulmonary disease (COPD). COPD is the name for a group of lung conditions that cause breathing difficulties.

F. Hoffmann-La Roche Ltd (Switzerland)
Sponsor

BP43098
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	between 35 and 75 years	No

Who can participate?
Patients aged 35 and 75 years who have had COPD for at least 1 year); please refer to the inclusion criteria

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group will receive RO7486967 and those in the other group will receive placebo capsules that look like RO7486967 but do not contain active medication. All participants will receive placebo for at least 14 days during the study.

What are the possible benefits and risks of participating?
There is no guarantee that participants will receive any benefits from this study, and taking part in this study may or may not cause their health to improve. Information from this study may help doctors learn more about RO7486967 and the treatment of COPD. This information may benefit other patients with COPD or a similar condition in the future. RO7486967 has been tested previously in healthy volunteers. Side effects seen were mild headache and nausea in some patients. The side effects resolved without additional treatment. The following are potential risks that may occur with RO7486967, but they have not been observed so far:

Liver toxicity (deterioration of liver function): some of the healthy volunteers who received RO7486967 in a previous study showed mild increase in the laboratory parameters used to evaluate the liver function. If patients have an abnormal blood test of liver function, they will not be included in this study. Liver function will be monitored closely during the study through blood tests.

Infection: RO7486967 works by inhibiting a protein complex called the NLRP3 inflammasome, which regulates the immune system. Inhibition of the immune system could result in increased susceptibility to infections. If patients have a known active infection, they will not be included in this study. Participants will be closely monitored for infections to ensure prompt treatment is received.

Impaired response to vaccinations: the NLRP3 inflammasome is activated by many vaccines and it ensures an adequate immune response to vaccination. Therefore, inhibition of the inflammasome may impair the response to vaccination. If participants require a vaccination, these should be completed at least 4 weeks prior to the first dose of study treatment. If participants plan to be vaccinated shortly after completing this study, they should discuss this with the study doctor.

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? June 2021 to May 2022

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

Who is the main contact? global-roche-genentech-trials@gene.com