ForPatients
by Roche

Ulcerative Colitis

A study to evaluate the safety, tolerability, processing by the body and mechanism of action of RO7486967 in participants with ulcerative colitis

Randomized, double-blind, sponsor-open, phase 1b study to assess the safety, pharmacokinetics and to explore the pharmacodynamics of RO7486967 in patients with moderate to severe active ulcerative colitis

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	1 Countries	BP43099

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

Trial Summary:

The purpose of this study is to test the safety of RO7486967 and to find out what effects, good or bad, RO7486967 has on participants. RO7486967 is a small chemical molecule that can inhibit the formation of a protein complex known as “inflammasome,” which could worsen the inflammation of participant’s intestine.

RO7486967 is an experimental drug, which means Health Authorities have not approved RO7486967 for the treatment of any diseases.

BP43099
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male and Female	18 to 75 years	No

Who can participate?
People aged between 18 to 75 years with moderate to severe active ulcerative colitis.

What does the study involve?
Participants will be randomly assigned by a computer program to one group (drug or placebo), i.e. randomized. This means that participants are put into a group by chance

(like tossing a coin). Neither a participant nor the study doctor may choose the group to be in. RO7486967 or placebo is provided in gelatin capsules which the participant needs to swallow with a bit of water. A participant will take 3 capsules each day for 7 days consecutively. The total length of time in the study, including the screening, dosing period(s), and follow-up periods, will be approximately 6 weeks. First part involves the study screening which includes discussion of the study, medical history check, physical examination, vital signs check, blood and urine sample collection, measurement of the electrical activity of the heart and pregnancy testing (if female). Then, RO7486967 or placebo is provided in gelatin capsules which one needs to swallow with a bit of water.

What are the possible benefits and risks of participating?
RO7486967 is being given to participants purely for research purposes; it is not intended that one will receive any benefit from it, as the treatment duration of 7 days is too short. New, more effective, and convenient medicines can only be developed by performing research studies such as this one. Information from this study may help doctors learn more about RO7486967 and the treatment of UC. Ultimately, it is the future patients who will hopefully benefit from the results of this study.
Participants may have side effects from the medications or procedures used in this study. However, Roche, the study doctor, and other doctors do not know all of the side effects that could occur. Side effects can vary from mild to very serious and may vary from person to person. Many side effects go away soon after participants stop what is causing them. In some cases, side effects can be serious (in very rare cases may be fatal) and may be long lasting or may never go away. Participants should talk to the study doctor about any side effects that one has have while taking part in the study. Everyone taking part in the study will be watched carefully for any side effects and cared for as appropriate. The study doctors may give medications to help lessen side effects.

Where is the study run from?
Charité Research Organisation GmbH

When is the study starting and how long is it expected to run for?
December 2020 to June 2022

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

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