ForPatients
by Roche

Cancer Healthy Volunteers

A study to look at how safe different doses of RO7497987 were for healthy people to take – and how this medicine was processed through the body

A Phase IA, open-label study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7497987 in single and multiple ascending doses in healthy volunteers

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	GO43310

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 clinical trial was done to study a new medicine called, “RO7497987,” a type of cancer treatment known as “cancer immunotherapy.” This study tested different doses of RO7497987. Researchers wanted to find out what doses healthy people could tolerate, and what the side effects were. This was a Phase 1a, open-label, study to look at safety, pharmacokinetics, and pharmacodynamics, when single and multiple doses of RO7497987 were given to healthy volunteers.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)
Sponsor

Phase 1a
Phase

GO43310
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 65 years	Yes

This was a Phase 1a, open-label study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7497987, an experimental cancer immunotherapy. Forty-four healthy volunteers were enrolled at one study center in five single-dose groups and two multiple-dose groups in the USA. Forty-three people completed the study. Results showed that treatment with RO7497987 in Study GO43310

was well tolerated across all doses tested. Ten people experienced side effects that researchers thought were caused by RO7497987. There were no serious side effects. No one in this study stopped taking RO7497987 because of side effects.

The aim of this study is to test the drug RO7497987 at different doses to find out if it is safe, to find out the effects of RO7497987 on the body, and to understand how the human body processes it. In this study, participants will receive either one or two dose(s) of RO7497987. RO7497987 is an experimental drug, which means health authorities have not approved RO7497987 for the treatment of any disease, and it has not been tested in people before this study.

Who can participate?
Healthy people aged between 18 to 65 years old.

What does the study involve?
Participants will be screened to see if they may participate in the study. During screening, participants undergo a physical examination and electrocardiogram (ECG), and blood and urine samples will be taken. In addition, their height, weight, and vital signs will be measured.

Participants will be placed in one of the following treatment groups. Group 1 will receive one dose of RO7497987 given as an infusion (into the vein). Group 2 will receive multiple doses of RO7497987, given as an infusion.

Treatment will be given in a clinic. Participants will be required to check into the treatment centre 1 day before they receive the study treatment, and the duration of time participants will stay in the treatment centre is based on the treatment assigned.

After the treatment period ends, participants will return to the clinic for follow-up visits. During these visits, participants will be asked about their well-being, their vital signs will be taken, and additional blood samples will be collected.

What are the possible benefits and risks of participating?
Participants will not receive any benefit from participating in this study, but the information that is learned may help people with certain cancers in the future.

The potential side effects related to the study drug, based on laboratory studies or knowledge of similar drugs, are listed below:

- Infusion-related or allergic reaction with symptoms such as fever, chills, etc
- Minimal to mild increase in liver enzymes
- Increase in the size of participant’s lymph nodes, spleen, or other organs

- Interactions with vaccine/immunisation
- There may be a risk in exposing an unborn child to the study drug, and all the risks are not known at this time.

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

When is the study starting and how long is it expected to run for?
June 2021 to April 2023

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

Who is the main contact?
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