Summary of Clinical Trial Results

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

See the end of the summary for the full title of the study.

About this summary

This is a summary of the results of a clinical trial (called a "study" in this document).

This summary is written for:

- Members of the public
- People who took part in the study

This summary is based on information known at the time of writing.

The study started in November 2021 and finished in January 2023. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. It takes many people in several studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

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Contents of the summary

Thank you to the people who took part in this study

The people who took part have helped researchers answer important questions about RO7497987, the study medicine.

Key information about this study

- This study was done to find out: What were the side effects after treatment with a new study medicine – RO7497987? Could people tolerate this medicine?
- People were given different doses of the study medicine – RO7497987 – through a vein (intravenously) – IV dosing.
- This study included 44 people in one country, the US.
- Ten people experienced side effects that study doctors thought were caused by RO7497987. There were no serious side effects in this study. No person in this study stopped taking RO7497987 because of side effects. In this study, people could tolerate RO7497987 at the doses tested.

1. General information about this study

Why was this study done?

"Cancer immunotherapy" (**CIT**) is a type of treatment that helps immune cells in the body find and kill cancer cells. Patients may have fewer and/or less severe side effects from CIT in comparison to chemotherapy.

Many people with cancer can live longer because of CIT. Unfortunately, not everyone responds to this treatment.

Researchers believe combining two different CIT medicines may improve patient outcomes. RO7497987 is an experimental medicine that researchers would like to combine with another CIT for treating patients with cancer.

This study tested different doses of RO7497987 as a single therapy. It was the first time RO7497987 was given to people. Researchers wanted to find out what doses healthy people could tolerate, and what the side effects were.

What was the study medicine?

The study medicine – **RO7497987** – also known as **FLT3L-Fc**, was made by joining (fusing) two proteins: FLT3L and Fc.

FLT3L is a signaling protein in the body that binds to immune cells to cause a reaction. Dendritic cells are one of many immune cells important for fighting cancer. FLT3L increases the number of dendritic cells in the body.

Fusing **Fc** to FLT3L causes FLT3L to stay in the body for a longer time. That means a longer time passes before people need another treatment dose of RO7497987.

What did researchers want to find out?

This was an early study to find answers that would help further research on RO7497987.

In this study, the main question that researchers wanted to answer was:

1. Was it safe to treat people with RO7497987?

What kind of study was this?

Here are some features of this study.

Phase 1 study
This was a "Phase 1" study, which means that this was an early study looking at RO7497987. A small number of healthy people got treatments. Researchers asked questions and did medical tests on the people to find out more about the treatments.

Single ascending dose (SAD) and multiple ascending dose (MAD) study
People who joined this study were assigned to different groups. The first group of people received the lowest dose of the study medicine. Then, each new group received the next higher dose. The decision to increase the dose in the next group was made after reviewing safety results from people who had already been treated in the lower dose group.
People in the SAD groups received a single treatment dose. People in the MAD groups received two treatment doses.

Open-label study
Researchers and people in the study knew that people in the study were getting RO7497987. That made it an "open-label" study.

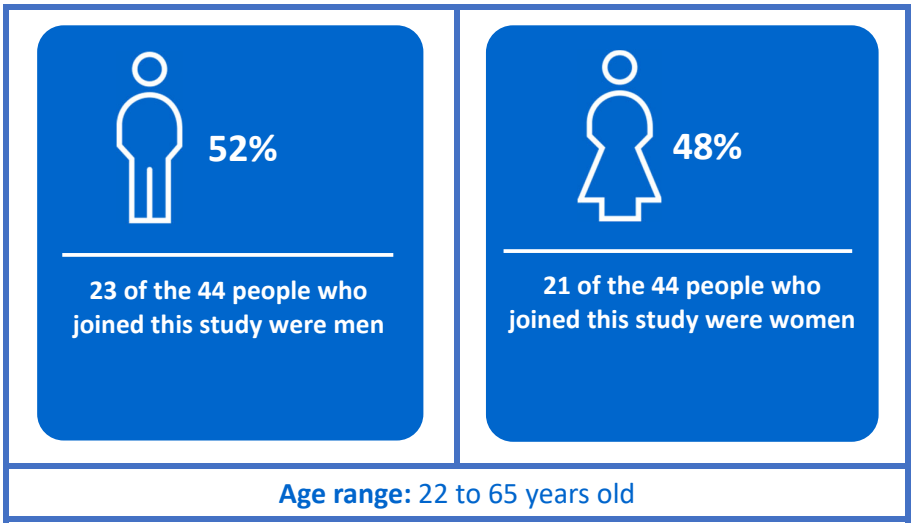
When and where did the study take place?

The study started in November 2021 and finished in January 2023. This summary was written after the study had ended.

The study took place at one study center in the US.

2. Who took part in this study?

Forty-four healthy people joined this study.



People could take part in the study if they met all of the following conditions:

- Male and female between the ages of 18 and 65 years
- A minimum weight of 40 kg and met the height/weight ratio (BMI 18-32 kg/m^2)
- Agreed to use birth control and refrain from donating sperm and eggs for a specified period
- Blood test results within acceptable range

People could not take part in the study if they met any one of the following conditions:

- Women who were pregnant, breastfeeding, or intended to become pregnant within 3 months of the last treatment dose
- Current health status, past health history, or family history that was not allowed
- Current medications and vaccinations or past treatments that were not allowed
- History of drug or alcohol abuse
- Current smoker, vape or tobacco product user
- Positive test for drug, alcohol, or tobacco use
- Donated blood or blood products during a restricted period

3. What happened during the study?

People were checked (screened) up to 30 days before study start day – to see if they met the requirements for joining the study.

Those who passed were allowed to join a group. There were five SAD and two MAD groups.

SAD groups: They came to the clinic a day before treatment (Day -1) and got their treatment on Day 1. They went home on Day 22. They returned to the clinic for follow-up visits until Day 50 for lower dose groups or until Day 85 for higher dose groups.

MAD groups: They came to the clinic a day before treatment (Day -1) and got their treatment on Day 1 and Day 22. They went home on Day 25. They returned to the clinic for follow-up visits until Day 106.

Treatments: Each SAD group got a different dose of the study medicine – RO7497987 – through a vein (intravenously) – IV dosing. Each MAD group got a different dose of the study medicine – RO7497987 – that was found to be safe in an earlier SAD group.

The first SAD and MAD groups to be treated got a low dose. The next SAD and MAD group got the next higher dose, but only when the researchers thought it was safe to increase the dose.

Researchers asked questions, collected blood samples, and did clinical tests at several time points before, during, and after the treatments.

4. What were the results of the study?

SAD group
Thirty-two people joined the SAD groups. One person withdrew from the study on Day 4 so blood samples for later time points were not collected. Another person did not receive the complete dose due to an infusion pump malfunction.

MAD group
Twelve people joined the MAD group, received their assigned dose, and completed the study.

Question 1: Was it safe to treat people with RO7497987?

Researchers looked at the number of side effects, and how severe they were. They also looked at the vital signs: pulse rate, temperature, breathing rate, and blood pressure. Blood samples taken throughout the study allowed researchers to find out if there were any changes in response to treatments.

The 44 people in this study tolerated all the doses of RO7497987 that were tested. Many people had side effects that were low grade and not serious. Nobody withdrew from the study due to side effects caused by RO7497987.

This section only shows the key results from this study. You can find information about all other results on the websites at the end of this summary (see Section 8).
Side effects are discussed in detail in the next section.

5. What were the side effects?

Serious side effects

A side effect is considered "serious" if it is life-threatening, needs hospital care, or causes lasting problems.

There were no serious side effects reported in this study.

There were no deaths due to side effects in this study. Side effects did not cause anyone to stop the treatment or lower the dose.

Most common side effects

During this study, 10 of the 44 people (23%) reported 18 side effects that researchers thought were caused by RO7497987.

The most common side effects – those that happened in two or more people – are shown in the following table. Some people had more than one side effect – this means that they are included in more than one row in the table.

Side effect	**How often did it occur?**
Muscle pain (myalgia)	4 people (9%)
Swollen lymph nodes (lymphadenopathy)	3 people (7%)
Headache	3 people (7%)

Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see Section 8.

6. How has this study helped research?

The information presented here is from a single study of 44 healthy people. There were no health benefits from this medicine for healthy people who participated in this study. Results from this study may be useful for further research – for finding new treatments for people with cancer.

No single study can tell us everything about the risks and benefits of a medicine. It takes many people in several studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

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7. Are there plans for other studies?

At the time of writing this summary, other studies looking at RO7497987 were not planned.

8. Where can I find more information?

You can find more information about this study on the websites listed below:

- https://www.isrctn.com/ISRCTN92655801
- https://forpatients.roche.com/en/trials/healthy-volunteers/a-study-to-evaluate-the-safety--tolerability--processing-by-the-0.html

Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/About.html
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

Who organized and paid for this study?

This study was organized and paid for by Genentech, Inc., South San Francisco, CA, USA. Genentech is part of F. Hoffmann-La Roche Ltd., with headquarters in Basel, Switzerland.

Full title of the study and other identifying information

The full title of this study is:

A Phase 1a, open-label study to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of RO7497987 in single and multiple ascending doses in healthy volunteers

The protocol number for this study is:

GO43310

The International Standard Randomized Controlled Trial Number for this study is:

ISRCTN92655801