

Summary of Clinical Trial Results

A study to look at how RO7223280 was broken down, processed and removed from 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) – written for:

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

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

The study started in July 2022 and finished in September 2022. 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 lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

- **This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment**

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Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about the development of new antibiotics for treating infections caused by bacteria that are resistant to current antibiotics, and the medicine studied – 'RO7223280'.

Key information about this study

- This study was done to look at what happened in the body to a new antibiotic that may work well against a type of bacteria called '*Acinetobacter baumannii*'
- In this study, people were given the medicine being studied (called 'RO7223280')
 - RO7223280 was labelled with a radioactive molecule ('carbon-14', or 14C) to allow researchers to detect it in samples of blood, urine and poo (faeces)
- This study included 6 people in 1 country (Netherlands)
- The main findings were:
 - 14C-labelled-RO7223280 was removed from the body in urine and faeces within 4 days, with similar levels found in urine and faeces
 - half of the dose of 14C-labelled-RO7223280 was removed from blood plasma after about 5 hours
- 14C-labelled-RO7223280 was well-tolerated with acceptable side effects – none of the people taking 14C-labelled-RO7223280 had serious side effects

1. General information about this study

Why was this study done?

Antibiotics are medicines used to prevent and treat infections caused by bacteria. However, bacteria can change over time so that antibiotics can no longer kill them – known as 'antibiotic resistance'.

'*Acinetobacter baumannii*' is a type of bacteria which is resistant to most antibiotics.

- You say this as 'a-sin-ee-to-bac-ter bau-man-eye'
- The name is shortened to '*A. baumannii*'

Antibiotic resistant-*A. baumannii* is a problem in hospitals, particularly for people with weakened immune systems, such as the elderly and very young. New treatments for *A. baumannii* infections are needed.

What was the medicine being studied?

RO7223280 is the medicine that was studied here.

- RO7223280 kills *Acinetobacter* bacteria in a different way than currently available antibiotics
- This may mean that RO7223280 can be used to treat people with *A. baumannii* infections that are resistant to other antibiotics
- In this study, RO7223280 was labelled with radioactive 'carbon-14' (14C) to make '14C-labelled-RO7223280'
 - 14C is commonly used in clinical studies at doses that are not harmful to the body to help researchers see where in the body new study medicines go

What did researchers want to find out?

- Researchers did this study to see how quickly 14C-labelled-RO7223280 moves about the body, is broken down and is removed from the body (see Section 4 ‘What were the results of the study?’)
- They also wanted to find out how safe RO7223280 was – by checking how many people had side effects after being given 14C-labelled-RO7223280 and seeing how serious they were (see Section 5 ‘What were the side effects?’)

The main question that researchers wanted to answer was:

1. What happened to 14C-labelled-RO7223280 in the body?

Other questions that researchers wanted to answer included:

2. How many people had side effects or serious side effects throughout the study?

What kind of study was this?

This study was a ‘phase I’ study, which means that this was one of the first studies for RO7223280. A small number of healthy people (without bacterial infection) were given 14C-labelled-RO7223280, and the researchers did medical tests on the people who took part.

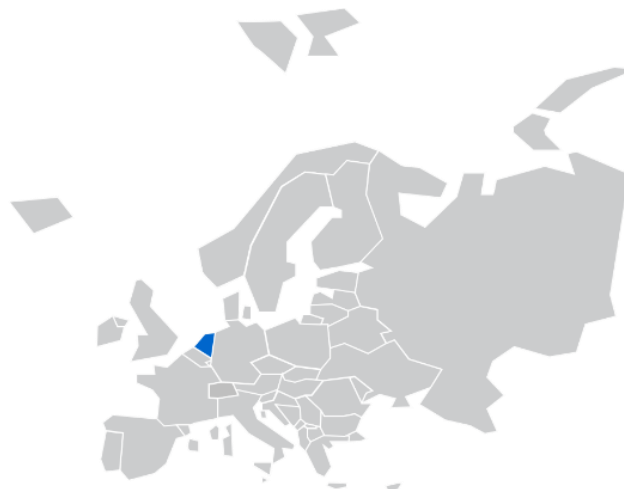
This was an ‘open label’ study. This means that both the people taking part in the study and the study doctors knew that people were being given 14C-labelled-RO7223280.

When and where did the study take place?

The study started in July 2022 and finished in September 2022. This summary was written after the study had ended.

The study took place at one study centre in the Netherlands, Europe.

- Netherlands



2. Who took part in this study?

In this study, 6 healthy men took part. Only men were asked to join for ethical reasons – to avoid exposing women of child-bearing age to radiation from the ^{14}C radioactive label on RO7223280 used in this study.

Men who took part in the study were between 37–61 years of age.

People could take part in the study if they were:

- Male and healthy
- Between 35–64 years old
- Had a body mass index (BMI) of 18–32kg/m²

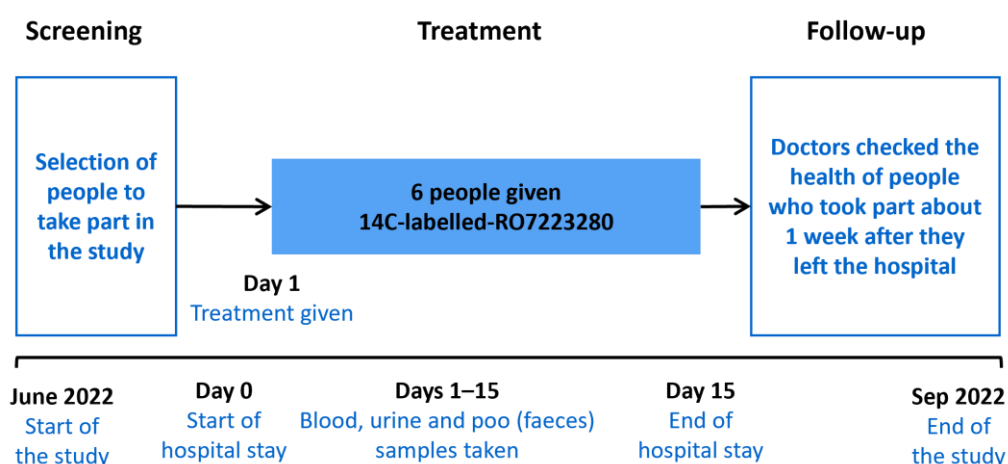
People could not take part in the study if they had:

- A history of or current medical conditions or certain diseases, including cancer, heart, lung or kidney problems
- Previously had surgery affecting the gut (digestive system)

3. What happened during the study?

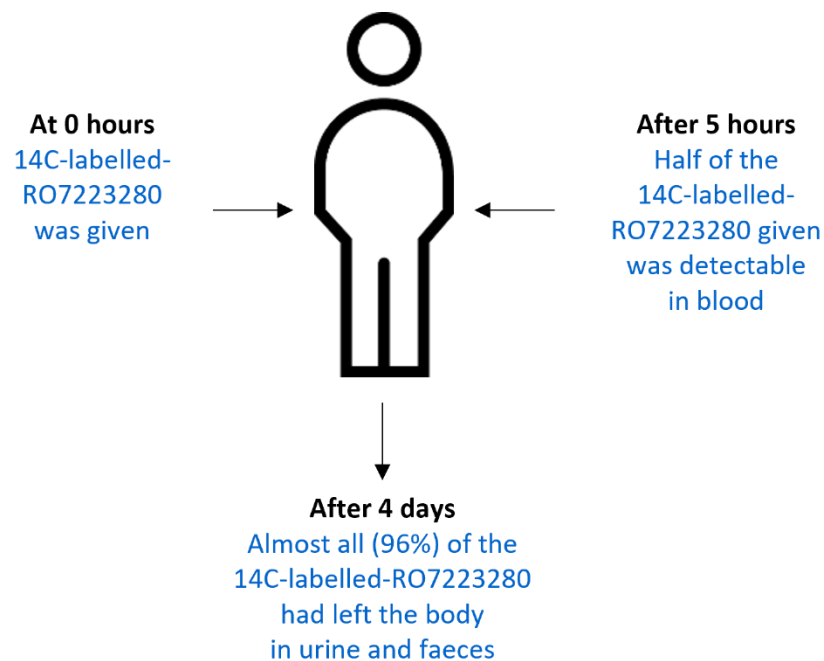
During the study, people stayed in the hospital for 15 days.

- After ‘screening’ to check that they met the criteria for the study, people were given a dose of ^{14}C -labelled-RO7223280 on Day 1
- Everyone was monitored in the hospital for side effects, and samples of blood, urine and poo (faeces) were taken daily over the 15 days
- Samples were checked to see how much ^{14}C -labelled-RO7223280 could be detected until almost all of it (95%) had been removed from the body



4. What were the results of the study?

Question 1: What happened to 14C-labelled-RO7223280 in the body?



- Most of the 14C-labelled-RO7223280 was detected in plasma – the liquid part of blood that carries nutrients, proteins and blood cells. This meant that 14C-labelled-RO7223280 did not interfere with red blood cells that carry oxygen around the body
- Similar amounts of 14C-labelled-RO7223280 were detected in urine and faeces

Question 2: How many people had side effects or serious side effects throughout the study?

- People in this study had mild and non-serious side effects only that were related to being given 14C-labelled-RO7223280
- 14C-labelled-RO7223280 was well-tolerated in this study with acceptable side effects

More information on side effects is shown in Section 5.

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).

5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that happen during the study.

- They are described in this summary because the study doctor believes the side effects were related to the treatments in the study
- Not all of the people in this study had all of the side effects
- Side effects may be mild to very serious and can be different from person to person
- It is important to be aware that the side effects reported here are from this single study. Therefore, the side effects shown here may be different from those seen in other studies
- Serious and common side effects are listed in the following sections

Serious side effects

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

During this study, none of the people who took part had a serious side effect or died.

Most common side effects

During this study, 4 out of 6 people (67%) had a side effect that was not considered serious.

- All 4 people had the same side effect – a reaction to 14C-labelled-RO7223280 (for example, redness and itching) within 24 hours
- This side effect was mild in severity in all 4 people

6. How has this study helped research?

The information presented here is from a single study of 6 healthy people. These results helped researchers learn more about the development of new antibiotics and RO7223280.

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- **This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment**

7. Are there plans for other studies?

Studies with RO7223280 are still happening, and further studies are planned.

8. Where can I find more information?

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

- <https://forpatients.roche.com/en/trials/healthy-volunteers/open-label--non-randomized-study-investigating-the-excretion-bal.html#forpatients>

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/trials/healthy-volunteers/open-label--non-randomized-study-investigating-the-excretion-bal.html#forpatients>
- 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 organised and paid for this study?

This study was organised and paid for by F. Hoffmann-La Roche Ltd who have their headquarters in Basel, Switzerland.

Full title of the study and other identifying information

The full title of this study is: 'Open-label, non-randomized study investigating the excretion balance, pharmacokinetics, and metabolism of a single intravenous dose of [14C]-labelled RO7223280 in healthy male participants'.

- The protocol number for this study is: BP43532
- The EudraCT number for this study is: 2022-001155-16