Summary of Clinical Trial Results

A study to look at how safe zosurabalpin is and how the body processes it in severely ill people with an infection caused by bacteria

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 December 2022 and finished in January 2024. 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.

Contents of the summary

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 medicine studied – 'zosurabalpin', which may be useful for the treatment of infections caused by bacteria that are resistant to current antibiotics.

Key information about this study

- This study was done to see what happens to a new medicine (called 'zosurabalpin') once it is in the body of severely ill people with an infection caused by bacteria. The aim of this study was to help doctors understand the best dose to use.
- In this study, people were given the medicine being studied, called zosurabalpin.
- Zosurabalpin is a new experimental antibiotic. Antibiotics are medicines used to treat infections caused by bacteria.
- Bacterial infections that can happen to people in hospital include lung infections that can cause cough, fever, and difficulty breathing (pneumonia).
- This study included 47 people in 3 countries.
- The main findings were:
    - In blood:
        - The highest amount of zosurabalpin was detected 1 hour after it started being given as a drip into a vein (infusion)
        - It took between 8 and 17 hours for half of the zosurabalpin to leave the blood
    - In lungs:
        - The highest amount of zosurabalpin was detected at 8 hours after the infusion
- No one taking zosurabalpin had serious unwanted effects that researchers considered related to zosurabalpin.

1. General information about this study

Why was this study done?

Bacterial infections are a problem in hospitals. They can cause issues such as pneumonia – a lung infection that can cause cough, fever, and difficulty breathing. They can cause people to become severely ill.

Antibiotics are medicines that treat infections caused by bacteria. But bacteria can become antibiotic resistant – a type of bacteria that survives treatment with antibiotics.

Therefore, new treatments for bacterial infections are needed.

A new medicine called 'zosurabalpin' may work well against bacteria that are resistant to other antibiotics. Previous studies have looked at what happens to zosurabalpin in the body when it is given to healthy people.

This study was done to find out what happens to zosurabalpin in the body when it is taken by severely ill people with an infection caused by bacteria. This was to help doctors understand the best dose to use.

What was the medicine being studied?

A medicine called 'zosurabalpin' was the focus of this study.

- You say this as 'zoss-yoora-BAL-pin'.
- Zosurabalpin kills bacteria in a different way to currently available antibiotics.
- This may mean that zosurabalpin can be used to treat people with infections that are resistant to other antibiotics.
- Zosurabalpin was tested at different doses.

What did researchers want to find out?

- Researchers did this study to see what happened to zosurabalpin in the body (see Section 4 "What were the results of the study?").
- They also wanted to find out how safe the medicine was – by checking how many people had unwanted effects and seeing how serious they were (see Section 5 "What were the unwanted effects?").

The main question that researchers wanted to answer was:

1. How much zosurabalpin got into the blood and lungs and for how long?

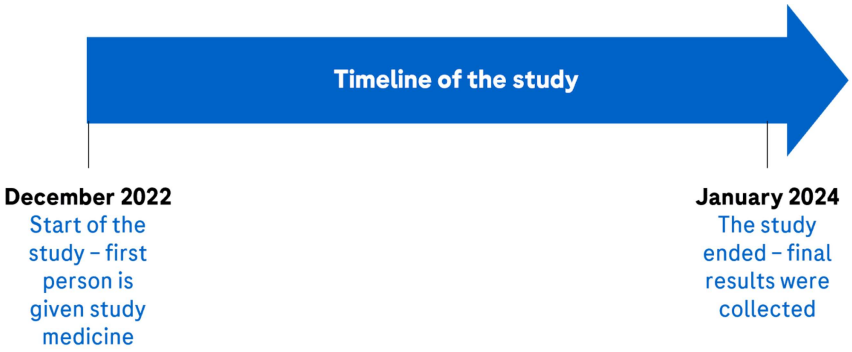
What kind of study was this?

This study was a 'Phase 1' study, which means that this was one of the first studies for zosurabalpin. A small number of people who were severely ill with a bacterial infection. Participants took a single dose of zosurabalpin so researchers could better understand how safe zosurabalpin is and how the body processes it. Researchers did medical tests on the people who took part to find out more about zosurabalpin.

This was an open-label study. This means everyone involved, including the participant and the study doctor, knew the participant was given zosurabalpin.

When and where did the study take place?

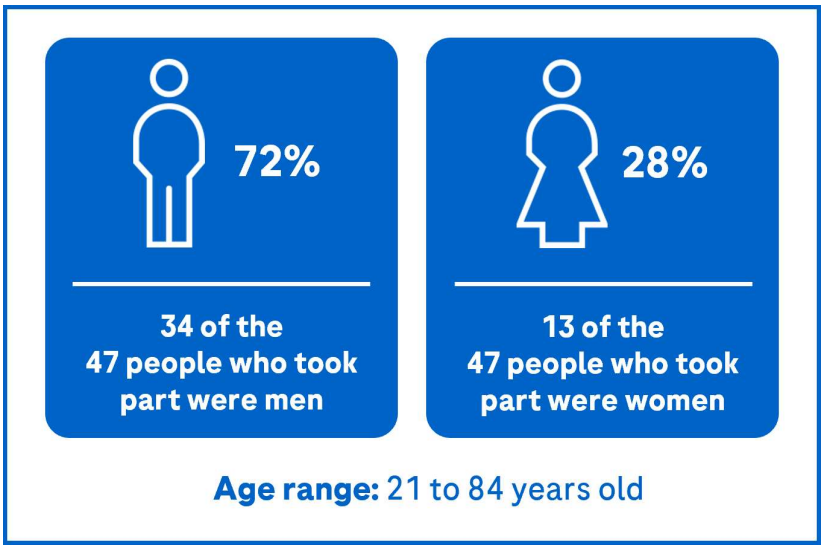
The study started in December 2022 and finished in January 2024. This summary was written after the study had ended.



The study took place at 5 study centres – across 3 countries in Europe and North America. The countries were: France, Moldova and the United States of America.

2. Who took part in this study?

In this study, 47 people who were severely ill with a bacterial infection took part. More information on the people who took part is given below.



People could take part in the study if:

- They were at least 18 years old.
- They were being treated in an intensive care unit and had an infection caused by bacteria.

People could not take part in the study if:

- They had major surgery or it was planned within 2 days of being given the study medicine.
- They had long-term serious liver problems.
- They had been treated with certain antibiotics or it was planned to treat within 2 days of being given the study medicine.
- They had been given zosurabalpin before.

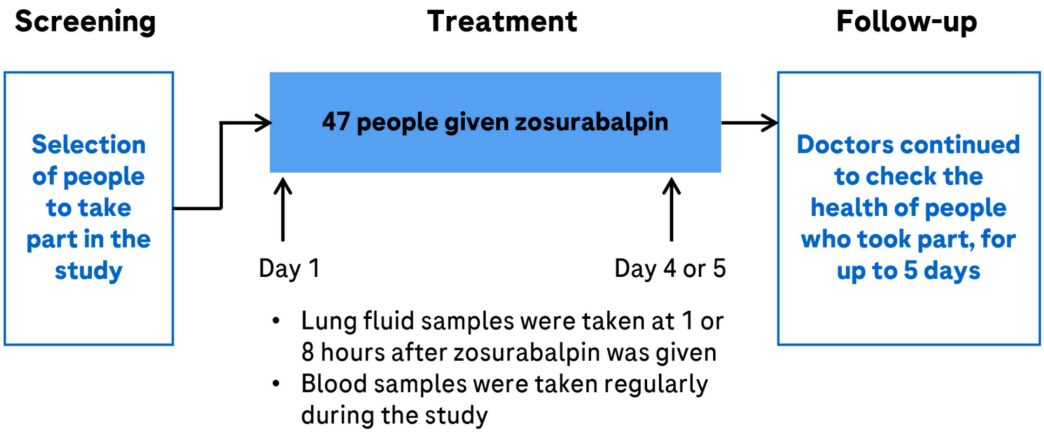
3. What happened during the study?

During the study, everyone who took part was given:

- Zosurabalpin (the medicine being studied) - a single dose as a drip into the vein (infusion) given over 1 hour

People in the study gave blood samples. Some people in the study had fluid removed from their lungs as part of their routine hospital care and a part of this fluid was given for the study.

The amount of zosurabalpin in blood and lungs was looked at to help researchers understand how much zosurabalpin should be given to people who are severely ill with a bacterial infection.



4. What were the results of the study?

Question 1: How much zosurabalpin got into the blood and lungs and for how long?

Researchers looked at how long it took for the highest level of zosurabalpin to be detected in the blood and the lungs. They also looked at how long it took for half of the zosurabalpin to leave the blood.

In blood:

- The highest amount of zosurabalpin was detected 1 hour after it started being given as a drip into a vein (infusion).
- It took between 8 and 17 hours for half of the zosurabalpin to leave the blood.

In lungs:

- The highest amount of zosurabalpin was detected at 8 hours after the infusion.

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 unwanted effects?

Serious unwanted effects

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

During this study, no one had a serious unwanted effect that researchers considered related to the study medicine.

No one in the study died due to unwanted effects that may have been related to the study medicine.

Most common unwanted effects

During this study, 6 out of every 100 people (6%) had an unwanted effect that was not considered serious and that was considered related to the study medicine. All unwanted effects were mild and not serious.

These were:

- 1 person out of 47 (2%) had low levels of the blood cell fragments that help the blood to clot. These cell fragments are called 'platelets'. This got better without treatment.
- 1 person out of 47 (2%) had cell damage in the liver. This got better without treatment.
- 1 person out of 47 (2%) had a reaction to the infusion that caused more blood to flow to the face and neck than usual. This was treated and got better within 4 hours.

Other unwanted effects

You can find information about other unwanted 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 47 people who were severely ill with bacterial infection. These results helped researchers learn more about bacterial infections and zosurabalpin.

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.

7. Are there plans for other studies?

Further studies with zosurabalpin are planned.

8. Where can I find more information?

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

- https://clinicaltrials.gov/ct2/show/results/NCT05614895
- https://www.clinicaltrialsregister.eu/ctr-search/trial/2022-000456-11/results
- https://forpatients.roche.com/en/trials/infectious-diseases/bacterial-infection/a-study-to-investigate-the-pharmacokinetics-of-ro722328-97260.html

If you would like to find out more about the results of this study, the full title of the relevant scientific paper is: ".....". The authors of the scientific paper are: <insert up to 5 author names, followed by 'and others'>. The paper is published in the journal '<insert journal name>', volume number <insert volume>, on pages <insert page range>. <A hyperlink must not be added here>

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/infectious-diseases/bacterial-infection/a-study-to-investigate-the-pharmacokinetics-of-ro722328-97260.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 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: "A Multicenter, Single-Dose, Uncontrolled, Open-Label, One Group Study to Investigate the Pharmacokinetics of RO7223280 in Critically Ill Patients with Bacterial Infections".

- The protocol number for this study is: BP43949.
- The ClinicalTrials.gov identifier for this study is: NCT05614895.
- The EudraCT number for this study is: 2022-000456-11.