Summary of Clinical Trial Results

A study to look at how zosurabalpin was processed through the body in people with healthy or diseased livers

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 January 2023 and finished in March 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 experimental medicine studied – 'zosurabalpin', which may be useful for the treatment of infections caused by a specific type of bacteria called Acinetobacter that is resistant to current antibiotics.

Key information about this study

- This study was done to understand if liver function affects how the experimental medicine being studied is processed by the body.
- The experimental medicine being studied was 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), and blood infections (sepsis).
- This study included 39 people in 3 countries.
- The main findings were:
    - The highest amount of zosurabalpin was found in the blood at the end of the 1 hour infusion, regardless of liver function
    - Liver function did not affect how zosurabalpin spread in the body, so peak levels in the blood were similar between people with different levels of liver function
    - The length of time it took for zosurabalpin to be removed from the blood varied greatly between people with the same level of liver function
    - There was no overall difference between groups of people with different levels of liver function.
- No one taking zosurabalpin had serious unwanted effects that were 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 blood infection (sepsis) and 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.

An experimental 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 people with mild, moderate, or severe liver disease, compared to people with healthy liver function. The liver helps remove drugs from the body and may take different amounts of time to do this in people with different levels of liver function. This means that different people may need different doses of zosurabalpin, depending on their liver function.

What was the medicine being studied?

An experimental 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.

What did researchers want to find out?

- Researchers did this study to see what happens to zosurabalpin in the body when it is taken by people with different levels of liver function (see Section 4 'What were the results of the study?').
- They also wanted to find out how safe the experimental 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. Does liver function affect how zosurabalpin moves through the body and how it is removed?

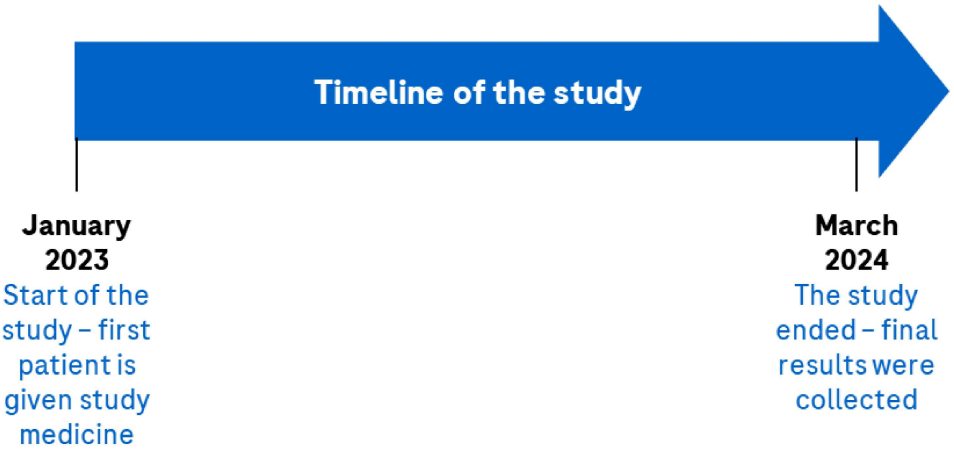
What kind of study was this?

This study was a 'Phase 1' study, which means that this was one of the first studies for zosurabalpin in humans. A small number of people who had different levels of liver function took zosurabalpin, and the 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 January 2023 and finished in March 2024. This summary was written after the study had ended.

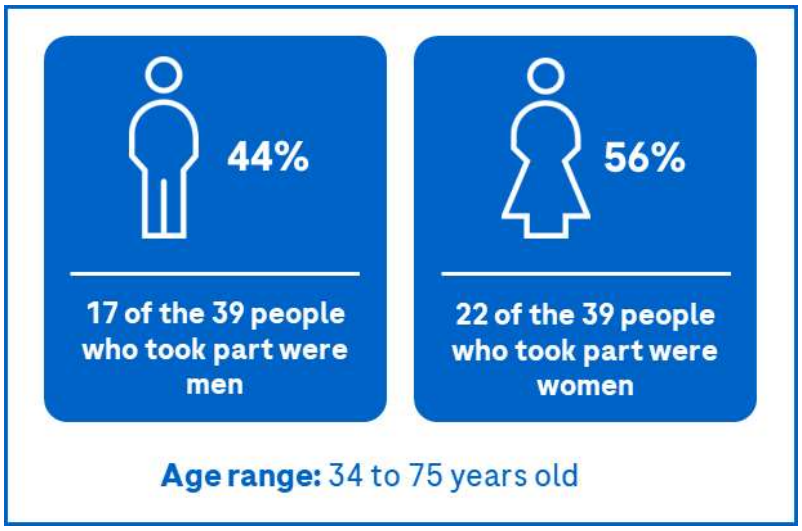


The study took place at 4 study centres – across 3 countries in Europe. The countries were: Germany, Poland and Slovakia.

2. Who took part in this study?

In this study, 39 people with or without liver disease 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.
- Weighed at least 50kg with a body mass index (BMI) of 18 to 40kg/m^2.

People could not take part in the study if they:

- Had any conditions that could affect how zosurabalpin is processed - like gallbladder removal or disorders that affect how the body absorbs nutrients from food (malabsorption).
- Had current or a history of heart problems.
- Had cancer within the last year.

3. What happened during the study?

During the study, everyone was given a single dose of zosurabalpin (the experimental medicine being studied) - via a drip into the vein (infusion).

People in the study gave blood samples before being given zosurabalpin, and for 4 days after.

When the study finished, the people who took part were asked to go back to their study centre for more visits – to check their overall health. Look below to see more information about what happened in the study.

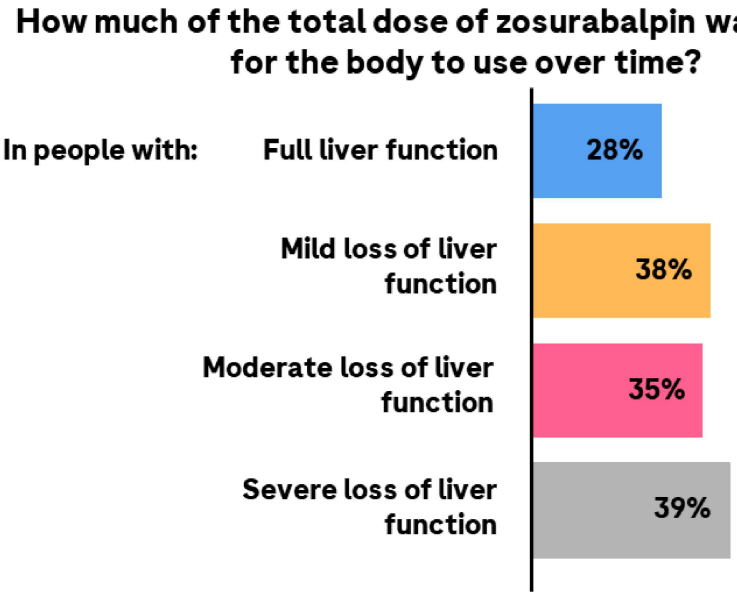
4. What were the results of the study?

Question: Does liver function affect how zosurabalpin moves through the body and how it is removed?

Researchers looked at how different levels of liver function affected how zosurabalpin gets to different parts of the body. Researchers did this to help find out if different people would need different doses of zosurabalpin, depending on their liver function. To find this out, the researchers looked at how long it took for the highest amount of zosurabalpin to be detected in the blood and how long it stayed in the blood.

There was no overall difference between groups of people with different levels of liver function:

- The highest amount of zosurabalpin was found in the blood at the end of the 1 hour infusion, regardless of liver function.
- The highest levels of zosurabalpin in the blood were similar between people with different levels of liver function.
- The length of time it took for zosurabalpin to be removed from the blood varied greatly between people with the same level of liver function.
    - This was measured in 'ug/ml' over time. A microgram (ug) is one-millionth of a gram, and millilitre (mL) is a unit of volume. So, using ug/mL is a way of saying how much of small amounts of a drug are in blood.



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?

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

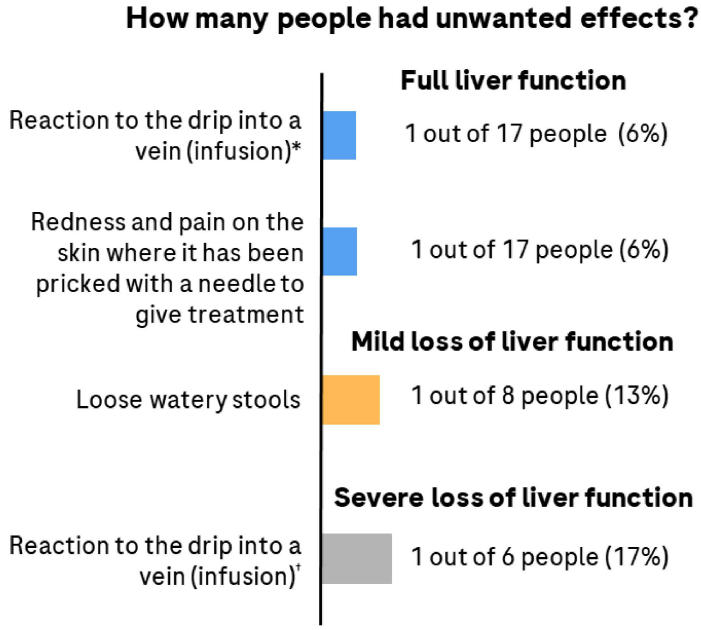
Serious unwanted effects

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.
- No one in the study died due to unwanted effects.
- No one decided to stop taking zosurabalpin because of unwanted effects.

Most common unwanted effects

During this study, 4 of the 39 people taking part (10%) had an unwanted effect that was considered related to the study medicine. The unwanted effects were not considered serious and all 4 people recovered.



*Symptoms were pain in the head and a sensation of feeling off balance, dizzy or spinning (vertigo). †Symptoms were feeling hot, changes in the sense of taste (making food taste strange or causing a strange taste in the mouth), belly pain and not having energy or strength.

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 39 people with different levels of liver function. These results helped researchers learn more about how liver function affects how zosurabalpin moves around the body, how quickly zosurabalpin is removed from the body and how safe it is. This helps researchers understand the best dose to give different people and plan future research studies.

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 experimental 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://forpatients.roche.com/en/trials/healthy-volunteers/a-multiple-center--open-label--non-randomized-study-to-investiga.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/trials/healthy-volunteers/a-multiple-center--open-label--non-randomized-study-to-investiga.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 multiple-center, open-label, non-randomized study to investigate the effect of various degrees of hepatic impairment on the pharmacokinetics of a single intravenous dose of RO7223280'.

- The protocol number for this study is: BP43792.
- The EudraCT number for this study is: 2022-002272-36.
- The ISRCTN number is: ISRCTN14383396.