

Summary of Clinical Trial Results

A clinical study to look for side effects of RO7020531 in healthy people and people with long-term hepatitis B

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 2016 and finished in June 2021. 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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Glossary

- Placebo = pretend medicine that has no effect
- NUCs = nucleoside and/or nucleotide analogs

Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about a liver infection called hepatitis B and the medicine studied – RO7020531.

Key information about this study

- This study was done to assess the side effects of RO7020531.
- In this study, people took different amounts of RO7020531 or placebo by mouth:
 - In Parts A and B, healthy people took RO7020531 or placebo once or for 2 weeks every other day.
 - In Part C, people with long-term hepatitis B took RO7020531 or placebo for 6 weeks every other day.
- This study included 160 people between 18 and 62 years of age in 8 countries.
- The main finding was that very few of the people who took RO7020531 had side effects that needed hospital care – see Section 4.

1. General information about this study

Why was this study done?

Some people with long-term hepatitis B take a medicine that treats infections caused by a virus (antiviral medication) to reduce or reverse liver problems and to prevent long-term problems of hepatitis B.

There are two types of antiviral medications:

- Nucleoside or nucleotide analogs, called ‘NUCs’ (these are medications that you take daily by mouth), and
- Interferons (these medications are injected weekly, just under the skin).

The current standard-of-care drugs have limitations. For example, people can get worse after stopping treatment. NUCs require long-term, sometimes lifelong treatment. Interferon treatment lasts about one year. People taking interferons commonly have flu-like symptoms. Also, the treatments can only stop the virus from making more virus copies. This reduces liver problems. But hepatitis B is rarely completely removed from the body. So, we need more effective and safe treatments to prevent the long-term effects of hepatitis B.

What was the medicine being studied?

This study looked at a medicine called RO7020531.

- Researchers expect that RO7020531 enhances the response of the immune system.
- This may mean that RO7020531 helps the immune system fight hepatitis B virus and keep it from harming the liver.

What did researchers want to find out?

- Researchers did this study to find out how safe the medicine was – by checking how many people had side effects when taking the medicine during this study and seeing how serious they were (see Section 5 “What were the side effects?”).

The main question that researchers wanted to answer was:

What were the side effects of RO7020531?

What kind of study was this?

This study was a 'Phase 1' study, which means that this was one of the first studies for RO7020531. A small number of healthy people and people with hepatitis B took RO7020531 or placebo, and the researchers did medical tests on the people who took part to find out more about RO7020531.

The study was 'randomised'. This means that it was decided by chance which of the medicines people in the study would have – like tossing a coin. Randomly choosing which medicine people take, makes it more likely that the types of people in both groups (for example, age, race) will be a similar mix. Apart from the exact medicines tested in each group, all other aspects of care were the same between the groups.

This study looked at the results from people taking RO7020531 and compared these with the results from people taking placebo. A 'placebo' (plah – see – bo) looks the same as a medicine but does not contain any real medicine. This means that it does not have any medicine-related effect on the body.

When and where did the study take place?

The study started in December 2016 and finished in June 2021. This summary was written after the study had ended.

The study took place at 12 study centres across 8 countries: Bulgaria, Hong Kong, Italy, Netherlands, New Zealand, Taiwan, Thailand, and United Kingdom.

2. Who took part in this study?

In total, 160 people took part in this study: 110 healthy people and 50 people with hepatitis B.

People who took part were between 18 and 62 years of age. 108 (67.5%) were men and 52 (32.5%) were women.

People could take part in Part A or B of the study if:

- They were healthy
- They did not take any drugs before the start of the study

People could take part in Part C if:

- They had hepatitis B for at least 6 months
- They had no other liver disease (than hepatitis B)

Some of the people in Part C had been taking NUC treatment for at least 6 months, the others had taken no treatment for hepatitis B in the last 6 months.

3. What happened during the study?

During the study, a computer decided by chance who was going to get RO7020531 or placebo.

People were given capsules of RO7020531 or placebo to swallow. The list below shows the treatment that people in each group took.

- **Part A; healthy people taking RO7020531 or placebo:**
64 people took between 3 mg and 170 mg RO7020531 and 16 people took placebo.
- **Part B; healthy people taking RO7020531 or placebo:**
24 people took between 100 mg and 170 mg RO7020531 every other day for 2 weeks and 6 people took placebo every other day for 2 weeks.
- **Part C; people with long-term hepatitis B taking RO7020531 or placebo:**
39 people took 150 mg or 170 mg RO7020531 every other day for 6 weeks and 11 people took placebo every other day for 6 weeks.

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.

4. Main result of the study: 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 can vary from 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, one (around 3%) of the 39 people with hepatitis B taking RO7020531 had a serious side effect, compared with none of the people taking placebo. The serious side effect was flu-like symptoms and it went away without long lasting problems.

No one in the study died due to side effects that may have been related to one of the study medicines.

During the study, 1 (around 3%) of the 39 people with hepatitis B taking RO7020531 decided to stop taking their study medicine because of side effects, compared with none of the people taking placebo.

Most common side effects

During this study, around 1 out of 25 (around 3%) healthy people who took RO7020531 once, had at least one side effect that was not serious.

Around 1 out of 3 (around 30%) healthy people who took RO7020531 for 2 weeks had at least one side effect that was not serious.

Around 1 out of 2 (around 51%) people with long-term hepatitis B who took RO7020531 for 6 weeks had at least one side effect that was not serious.

Common side effects are those that at least 1 person out of 10 had. Some people had more than one side effect.

There was no side effect that affected at least one out of ten people among the healthy people who took RO7020531 once.

The most common side effects in healthy people taking RO7020531 for 2 weeks were headache (1 out of 4 people [around 25%]), fever (1 out of 10 people [around 10%]) and nausea (1 out of 10 people [around 12%]).

The most common side effect in people with hepatitis B taking RO7020531 for 6 weeks were headache (18%), flu-like symptoms (18%), muscle pain (18%) and fever (15%).

Other side effects

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

5. How has this study helped research?

The information presented here is from a single study of 160 people; 110 healthy people and 50 people with long-term hepatitis B. These results helped researchers learn more about hepatitis B and the side effects of RO7020531.

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6. Are there plans for other studies?

At the time of writing this summary, one more study looking at RO7020531 is ongoing.

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/NCT02956850?view=results>
- <https://forpatients.roche.com/en/trials/infectious-diseases/hbv/a-study-in-healthy-volunteers-and-in-participants-with-chronic-h.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 (“Contact Us”) – <https://forpatients.roche.com/en/trials/infectious-diseases/hbv/a-study-in-healthy-volunteers-and-in-participants-with-chronic-h.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 Phase I, Sponsor-Open, Investigator-Blinded, Subject-Blinded, Multi-center, Placebo-Controlled Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Oral Administration of RO7020531: (1). Single and Multiple Ascending Doses in Healthy Male and Female Subjects; (2). 6-Week Treatment of Patients with Chronic Hepatitis B Virus Infection”.

- The protocol number for this study is: NP39305.
- The ClinicalTrials.gov identifier for this study is: NCT02956850.
- The EudraCT number for this study is: 2016-003723-38.