ForPatients
by Roche

Liver Failure

A study investigating the effect of various degrees of liver function impairment on the absorption and elimination of RO7434656, a new compound for the treatment of immunoglobulin A nephropathy

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	2023-508270-29-00 WA45032

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A multiple-center, open-label, non#randomised study to evaluate the effects of various degrees of hepatic impairment on the pharmacokinetics of a single subcutaneous dose of RO7434656, an antisense inhibitor of complement factor B

Trial Summary:

Hoffmann-La Roche	Phase 1
Sponsor	Phase

2023-508270-29-00 WA45032
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 84 years	No

1. Why is the WA45032 clinical trial needed?

Researchers are looking for better treatments for immunoglobulin A nephropathy (IgA nephropathy). RO7434656 is a new drug compound that may potentially be used for this purpose. A specific protein called complement factor B (CFB), a part of the immune system called the complement system, may play a role in causing kidney injury in patients with IgA nephropathy. RO7434656 can block CFB from being formed in the body. By doing so, RO7434656 offers a potential new treatment option for patients with IgA nephropathy by possibly decreasing inflammatory damage to the kidneys. RO7434656 has been extensively tested in the laboratory and in animals. It has also been tested in several

clinical trials involving healthy participants, patients with IgA nephropathy, and other diseases, though it has not been approved for general prescription.

Changes to the dose or dose frequency of many drugs are necessary when participants with impaired liver (hepatic) function are treated, because serious liver disease can cause changes to the metabolism and elimination of drugs. Therefore, to achieve safe and successful treatment outcomes, it is necessary to understand the potential need for dose changes in this specific patient group.

2. How does the WA45032 clinical trial work?

This clinical trial is recruiting people with mild, moderate or severe liver impairment, as well as participants with normal liver function; those with normal liver function will be compared to those with liver impairment, to observe to what extent RO7434656 is absorbed, distributed, metabolised and eliminated from the body. The effect of RO7434656 on different parts of the complement system will also be assessed.

Participation will be up to about 17 weeks: up to 90 days for screening, a stay at the research centre of five consecutive days, followed by three short follow-up appointments during the four weeks after staying at the research centre. Participants can stop trial treatment and leave the clinical trial at any time.

People who are eligible to participate will be given RO7434656 as a single dose whilst staying at the research centre. The five day stay in the research centre, as well as the follow up visits, will include checks to see how the participant responds to the treatment and any side effects they may have.

3. What are the main endpoints of the WA45032 clinical trial?

The main clinical trial endpoint (the main result measured in the trial) is the concentration of RO7434656 in the blood over time after administration of RO7434656.

The other clinical trial endpoints include measuring the number and severity of side effects and the occurrences of medical examination abnormalities after administration of RO7434656. Examinations include physical examinations, heart tracings, routine blood and urine laboratory tests and the measurement of blood pressure, pulse rate, number of breaths per minute and body temperature. The change in CFB levels and related markers in the blood will also be assessed.

4. Who can take part in this clinical trial?

People can take part in this trial if they are aged between 18 and 75 years old, have a body mass index of 18 - 38 kg/m2 and be vaccinated against - or be willing to receive a vaccination for - bacteria that can cause meningitis and pneumonia. Participants with

impaired liver function should have chronic stable liver disease. Women must be willing to use appropriate contraception to prevent pregnancies.

People will not be able to take part in this trial if they have had a history of cancer within the previous 12 months, a history of uncontrolled diabetes, have received a functioning organ transplant or are waiting for an organ transplant, or have uncontrolled high blood pressure.

5. What treatment will participants be given in this clinical trial?

Participants will receive one single injection of RO7434656 given under the skin (subcutaneous injection).

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the RO7434656 used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly.

RO7434656 (study drug)
Participants will be told about the known side effects of RO7434656, and possible side effects based on human and laboratory studies or knowledge of similar drugs. RO7434656 has been well tolerated in studies with healthy participants, however RO7434656 may cause side effects. All known and potential side effects will be listed in the informed consent document. RO7434656 will be given by an injection under the skin, known as a subcutaneous injection. Participants will be told about any known side effects of subcutaneous injections.

Potential benefits associated with the clinical trial
Participants will not benefit directly from participation in this study. Their participation will help the researchers learn more about the effects of RO7434656, and will help in the search for a better treatment of IgA nephropathy.