ForPatients
by Roche

Bacterial Infection

A multiple-center, non-randomized, open-label study to investigate the effect of various degrees of renal impairment on the pharmacokinetics of a single intravenous dose of RO7223280

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	2 Countries	BP43628

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

A study to evaluate the effects of various degrees of reduced kidney function on how the study drug (RO7223280) is broken down and eliminated from the body

F. Hoffmann-La Roche Sponsor	**Phase I** Phase

BP43628
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 82 years inclusive	Yes

Background and study aims

RO7223280 is an experimental drug that is being tested in this clinical study for the treatment of a disease (infection) caused by a germ (bacteria) called Acinetobacter baumannii. RO7223280 is an experimental drug, which means it is not approved by the Health Authorities for the treatment of bacterial infection caused by Acinetobacter baumannii or for any other disease. The aim of this study is to find out how different severity levels of kidney damage will affect the breakdown and removal of the study drug (RO7223280) from the body (this is called pharmacokinetics [PK]).

Who can participate?

People who are 18 to 82 years of age (inclusive), with normal kidney function, or mild, moderate, severe kidney damage or have end-stage kidney disease (ESRD) requiring their blood to be purified using a machine at regular intervals (hemodialysis).

What does the study involve?

Participants with normal kidney function, or mild, moderate, or severe kidney damage will have to be a part of this study for around 5 weeks. The study will be conducted as follows:

- Screening visit: Participants will have one screening visit. This will take place up to 28 days before the study drug administration to see if participants are eligible for the study.
- Treatment (residential) period: Participants will have to report to the clinic 2 days before the study drug administration (Day –2) and stay in the clinic up to Day 4.
- Follow-up visit: To check on the participant after the study treatment is finished. This visit will take place between 5 to 9 days after the study drug administration.

Participants with end-stage renal disease will have to be a part of this study for around 9 weeks. The study will be conducted as follows:

- Screening visit: Participants will have one screening visit. This will take place up to 28 days before the study drug administration to see if participants are eligible for the study.
- Treatment (residential) Periods 1 and 2: Participants will have to report to the clinic 1 day before the first study drug administration (Day –1) and stay in the clinic until Day 2, when they will be discharged during Period 1. After a period of 7-21 days wherein no drug will be given (washout period) the participants will have to report back to the clinic for Period 2, one day before the second study drug administration (Day –1) and stay in the clinic until Day 2.
- Ambulatory visit in Periods 1 and 2: Participants will have to visit the clinic on Day 4 (±1 day) and Day 7 (±1 day) after the first study drug administration in Period 1 and again on Day 4 (±1 day) and Day 7 (±1 day) of Period 2 after the second study drug administration.
- Follow-up visit in Period 2: To check on the participant after the study treatment is finished. This visit will take place 11 to 15 days after the second study drug administration.

What are the possible benefits and risks of participating?

Participants will not receive any benefit from this study but the information that is learned may help other people suffering from similar conditions in the future. Participants will receive monetary compensation for taking part in the study.

Participants may have side effects from RO7223280, or procedures used in this study. These can be mild to severe and even life-threatening, and they can vary from person to person. RO7223280 has had limited testing in humans and there may be side effects that are not known at this time. The potential side effects associated with RO7223280, and other procedures are listed below:

- Allergic reactions due to administration of RO7223280, which can be in the form of itching, difficulty breathing, a rash, and/or drop in blood pressure.
- There may be some changes in liver and kidney functions.
- Participants may experience symptoms like chills, fever, nausea, headache, high or low blood pressure, fast heart rate, and shortness of breath, itching at the site of injection

Iohexol is a dye (contrast media) which helps in measuring kidney function. The dose of iohexol being administered is significantly low and therefore the risk of side effects is also significantly lower.

There may be a risk in exposing an unborn child to the study drug, and not all potential risks are known at this time. Women and men must take precautions to avoid exposing an unborn child or a breastfed baby to the study treatment. Participants who are pregnant, or breastfeeding cannot take part in this study.