ForPatients
by Roche

Healthy Volunteers

A non-randomized, open-label, single-dose study to investigate the intrapulmonary penetration of RO7223280 following intravenous administration in healthy participants

Trial Status	Trial Runs In	Trial Identifier
Recruiting	0 Countries	ISRCTN16112706 BP43629

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 investigate the lung penetration of RO7223280 following intravenous administration in healthy participants

F. Hoffmann-La Roche Ltd (USA)
Sponsor

Phase I
Phase

ISRCTN16112706 BP43629
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 55 years	Yes

Background and study aims:

Antibiotic-resistant bacterial infections are an urgent global threat to public health. Antibiotic resistance happens when germs such as bacteria develop the ability to defeat the drugs designed to kill them. The treatment of the multi-drug resistant (MDR) bacteria Acinetobacter baumannii is extremely challenging because of high rates of resistance to multiple antibiotics. This is a clinical study of a new (novel) drug called RO7223280 which is being developed for the possible treatment of infections caused by the bacterium Acinetobacter baumannii. RO7223280 is an experimental drug and is not yet approved by health authorities like the U.S. Food and Drug Administration for the treatment of bacterial infections.

The main purposes of this study are:

1. To measure the amount of RO7223280 that gets into the lungs and how quickly the body processes it (also called pharmacokinetics [PK])

2. To assess the safety of RO7223280 and determine how well the participants tolerate it.

Who can participate?

Healthy volunteers who are between 18 to 55 years of age, inclusive

What does the study involve?

Participants will need to be a part of this study for about 5 weeks. This study will have three parts:

1. Screening period: Up to 4 weeks before the start of study treatment administration. During this period, the study doctor (also called an Investigator) will conduct certain tests and/or procedures, to make sure that the participants are eligible to participate in this study.

2. Treatment (residential) period: During this period, the participants will have to report to the clinic 1 day before the treatment administration (Day -1) and stay in the clinic for 4 nights. The participants will receive a single dose of 1000 mg RO7223280 over 1 hour through a tube put into a vein in the arm (intravenous infusion) on Day 1.

Each participant will then have a procedure called bronchoalveolar lavage (BAL) to measure the amount of study drug that goes into the lungs. This procedure will be scheduled up to 8 hours after the end of the study drug infusion. A bronchoalveolar lavage involves a flexible tube inserted through the participant's mouth into one of their lungs. A small amount of fluid (made up of salt and water) will be sprayed into the lung from the tube and then immediately suctioned back to collect lung fluid and cells for examination. During this procedure, a local numbing drug (anaesthetic), such as lidocaine, will be sprayed into the participant's mouth and throat to numb the mouth, nose, and gag reflex.

The participants will have to fast for at least 2 hours before study drug administration and at least 4 hours before undergoing the BAL procedure.

3. Follow-up period: This will take place about 7 days after the study treatment administration to check on the participant after treatment completion. The participant will have to visit the clinic for the follow-up procedures.

What are the possible benefits and risks of participating?

Participants will be administered RO7223280 only for research purposes and it is not intended that the participants will receive any benefit from it. However, the information

learned in this study may help future patients suffering from Acinetobacter baumannii infection.

Participants will be compensated for taking part in this research study. Participants will be compensated for each part of the study they complete up to a total amount of $2700. All study participants will be issued their compensation within 21 days of the completion of their participation in the study.

Participants may experience side effects from the treatments or procedures in this study. Side effects can vary from mild to serious and may be different from person to person. As RO7223280 is a new experimental drug with limited exposure in humans, not all the side effects that could occur are known at this time. The known side effects, as well as potential side effects of this drug based on human and laboratory studies, or knowledge of similar drugs, are listed below:

Allergic reactions: these can be in the form of itching, difficulty breathing, a rash, and/or a drop in blood pressure. In very rare cases, participants could have a life-threatening allergic reaction. Infusion-related reactions: these side effects are related to the administration of the study drug as an intravenous infusion. Symptoms may include itching, flushing, and shortness of breath. Other common side effects, seen were headache and side effects associated with either patches from the device used to record the heart’s activity (electrocardiogram [ECG]) or the infusion needle (e.g., skin inflammation (swelling), skin bruising).

As the study treatment is given through a needle placed in the participant's arm, they may experience mild discomfort during the procedure, and there is a small chance of infection from placing the needle in their arm.

Spirometry is a common test used to assess how well the lungs work by measuring how much air is breathed in and out and how quickly air is breathed out. Spirometry is generally a safe test, though it may require some exertion. Participants may feel short of breath or dizzy for a moment after they perform the test.

During the bronchoalveolar lavage (BAL) procedure participants may experience coughing or gaging as the bronchoscope will be inserted through their mouth. The coughing or gagging will stop as the numbing drug begins to work. Potential risks associated with BAL include irritation of the airways (bronchospasm), irritation of the vocal cords (laryngospasm), cough, temporary fever, temporary chills, and muscle pain, and there may be some short-lived difficulty with breathing. Less frequent risks include bleeding, infection, a hole in the airway (bronchial perforation), air in the space between the lung covering (pleural space) that causes the lung to collapse (pneumothorax). Participants may have an allergic reaction to the local numbing drug (e.g., lidocaine). Common side effects of lidocaine are feeling hot or cold, nausea and vomiting, drowsiness, dizziness.

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

Where is the study run from?

F. Hoffmann-La Roche Ltd (USA)

When is the study starting and how long is it expected to run for?

December 2021 to September 2022

Who is funding the study?

F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?

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