ForPatients
by Roche

A Study to Investigate the Pharmacokinetics of RO7223280 in Critically Ill Participants With Bacterial Infections

Trial Status	Trial Runs In	Trial Identifier
Undefined	0 Countries	NCT05614895 2022-000456-11, ISRCTN21709018 BP43949

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

Trial Summary:

The main aim of the study is to investigate the plasma pharmacokinetics (PK) and safety of intravenous (IV) administration of a single dose of 400 milligrams (mg) or 600 mg RO7223280 in critically ill participants with bacterial infections.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

Background and study aims:

Nosocomial bacterial pneumonia is an infection of the lungs. Bacteraemia is an infection of blood. Both are severe invasive infections caused by bacteria. The drug under study (RO7223280) is being developed for the possible treatment of such infections. RO7223280 is an experimental drug i.e., the Health Authorities (like the U.S Food and Drug Administration and European Medicines Agency) have not approved RO7223280 for the treatment of infections. The main purpose of this study is: -

To measure the drug levels in the body

To determine the safety of the drug

Who can participate?

Participants who are over 18 years of age and are critically ill because of hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), or bacteraemia.

What does the study involve?

The maximum length of participation in the study is about 9 days.

The study will include:

1. Screening period: The screening period will last up to 5 days. All participants will be screened to make sure they are a good fit for the study.

2. Treatment period: All participants will receive a single dose of 600 mg of RO7223280 over 1 hour through a needle put into a vein in the arm (infusion) on Day 1. The participants will have to stay in hospital during the treatment. Some blood samples will be taken on Day 1.

3. Safety Follow-up Period: Additional blood samples will be taken on Days 2 and 3. Participants will have a check-up on Days 2 to 4 after the treatment period.

What are the possible benefits and risks of participating?

Participants may not receive any health benefit from participating in this study, but the information learned in this study may help patients with similar conditions in the future. Participants may experience side effects from the study drug, and these can be mild to severe and can vary from person to person. RO7223280 has had limited testing in humans. The known side effects of this drug, as well as potential side effects are listed below. There may potentially also be side effects that are not known at this time.

Itching

Flushing

Shortness of breath

Headache

Skin inflammation

Skin bruising

There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn

child to study drug. Participants who are pregnant, become pregnant, or are currently breastfeeding cannot take part in this study.