ForPatients
by Roche

Bacterial Infection

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

Trial Status	Trial Runs In	Trial Identifier
Completed	5 Countries	NCT05614895 2022-000456-11 ISRCTN21709018 BP43949

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 Multicenter, Single-Dose, Uncontrolled, Open-label, One Group Study to Investigate the Pharmacokinetics of RO7223280 in Critically Ill Patients With Bacterial Infections

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	Phase 1
Sponsor	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.

Inclusion Criteria:

- Illness requiring treatment in an intensive care unit (ICU) at the time of enrolment
- Ongoing clinical syndrome meeting at least one of the following criteria:

1. HABP: bacterial pneumonia diagnosed after more than 48 hours of hospitalization or within 7 days after a hospital discharge

2. Ventilator-associated bacterial pneumonia (VABP): bacterial pneumonia diagnosed after more than 48 hours of mechanical ventilation or within 72 hours after weaning

3. Bacteremia confirmed by the presence of a bacterial pathogen in a blood culture drawn within 7 days prior to dosing and with the defined focus of infection.

4. For Cohort 4 only: mechanically ventilated participants who have a BAL procedure planned as part of routine practice for a day that can function as Day 1.

Exclusion Criteria:

- Ongoing documented catheter-related bacteraemia as the sole ongoing infection
- Major surgery within 48 hours prior to dosing or major surgery expected within 48 hours after the start of the infusion
- Known chronic severe hepatic impairment (Child-Pugh class C). Note: acute severe hepatic impairment is not exclusionary