ForPatients
by Roche

Infectious Diseases

A sponsor-open, randomized, placebo-controlled, phase I study to investigate the pharmacokinetics, safety, and tolerability of RO7223280 in healthy Chinese participants following single IV dose administration

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	BP44069

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 safety, tolerability, and processing by the body of RO7223280 following single-dose administration in healthy Chinese participants

F. Hoffmann-La Roche Ltd (USA)
Sponsor

Phase 1
Phase

BP44069
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 64 years	Yes

Background and study aims The study drug RO7223280 is being developed for the possible treatment of bacterial infection caused by the bacteria Acinetobacter baumannii. RO7223280 is an experimental drug, which means Health Authorities have not approved RO7223280 for treating any bacterial infection. This study aims to test the safety of RO7223280 at different dose levels and to find out the effects, good or bad, of RO7223280 on the study participants.

Who can participate? Healthy Chinese males and females aged between 18 and 64 years old

What does the study involve? Participants will have to be a part of the study for about 6#weeks (from screening to follow-up), which will be divided as follows:

ForPatients
by Roche

Screening Period: To check if the participants are eligible for the study. This visit will occur up to 28 days before the study treatment administration.
Treatment Period (residential/in-house): The participant will need to come to the clinic 1 day before the treatment administration (Day –1) and stay in the clinic for 5 nights (from Day -1 to Day 5).

Participants will be randomly assigned to one of the treatment groups to receive one single IV dose of either 600 milligrams (mg), 1000 mg, or 1500 mg of RO7223280 or a placebo (a substance that looks like the study drug but contains no active medication) through a tube or cannula introduced into a vein in the arm (intravenous infusion) on Day 1 of the treatment period.

Follow-up: To check on the participant after treatment is finished. This visit will occur approximately 14#days after the last study treatment administration.

What are the possible benefits and risks of participating? RO7223280 is being given purely for research purposes, it is not intended for participants to receive any benefit from it. Future patients may benefit from the information collected in this study.

Participants may experience side effects from the study treatment or procedure. The side effects can vary from mild to very serious and may be different from person to person. RO7223280 has had limited testing in humans and not all side effects are known at this time.

The most common side effect includes infusion-related reactions (e.g., itching, flushing, shortness of breath). Other side effects include headache and side effects that are associated with either patch from the device that is used to monitor the heart electrocardiogram (ECG) or from the needle used to inject the drug (e.g., skin swelling (inflammation), skin bruising).

There may be a risk in exposing an unborn child to the study treatment, and not all potential consequences 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, become pregnant, or are currently breastfeeding cannot take part in this study.

Where is the study run from? F. Hoffmann-La Roche Ltd (Switzerland)

Who is funding the study?
F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?
global-roche-genentech-trials@gene.com