ForPatients
by Roche

Healthy Volunteers

A non-randomized, open-label, non-controlled, adaptive, multiple-dose study to investigate the safety, tolerability, and pharmacokinetics of zosurabalpin following intravenous administration in healthy participants

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	BP44773

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 assess safety, tolerability, and processing by the body of multiple doses of zosurabalpin administered through a tube inserted into a vein in the arm of healthy participants

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

BP44773
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 64 years	Yes

Background and study aims:

Acinetobacter is a group of germs (bacteria) commonly found in soil and water causing infections in different parts of the body such as blood, urinary tract, and lungs. These bacteria are constantly finding new ways to defeat the effects of the drugs used to kill them (antibiotics) and treat the infections they cause. This is called antibiotic-resistance. Carbapenems were a mainstay of treatment for antibiotic-resistant acinetobacter. However, these bacteria have developed resistance to carbapenems too. Zosurabalpin is an experimental drug, which means that Health Authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved zosurabalpin for the treatment of antibiotic-resistant bacterial infections.

The purpose of this study is to find out whether zosurabalpin at different doses has any effects (good or bad) and what happens to zosurabalpin once it is in the participant's body (this is called pharmacokinetics [PK]).

Who can participate?

Healthy males and females of 18 to 64 years of age

What does the study involve?

Participants will need to be a part of this study for about 8 weeks. The study will have four parts:

1. Screening Period: Potential participants will be screened to check if they are eligible to participate in the study. Screening visit will take place from up to 32 days until 4 days before study treatment.

2. Treatment period: Participants will have to come to the clinic 3 days before the start of the study treatment (i.e., zosurabalpin). The study treatment will be administered via a tube inserted into vein in participant's arm from Day 1 to Day 10 and the participants will have to stay in the clinic until all assessments are completed on Day 14.

3. Ambulatory Visit: Participants will have to revisit the clinic on Day 16 after being discharged to assess the potential effects of zosurabalpin on the body.

4. Follow-up Visit: Participants will have to come back to the clinic again on Day 24 (+ or - 2 days) so that the study doctors can check the participants' health after treatment is completed.

What are the possible benefits and risks of participating?

Participants will receive zosurabalpin purely for research purposes; it is not intended that they will receive any benefit from it. The participants will not receive any additional benefit from participating in this study, but the information that is learned may help people with antibiotic-resistant bacterial infections.

Participants may have side effects from the drug or procedures used in this study, and they can be mild to severe, and they can vary from person to person.

Risks associated with zosurabalpin:

Zosurabalpin has had limited testing in humans; therefore, all the potential side effects are not known at this time. The known side effects of this drug, as well as potential side effects are listed below.

1. Allergic reactions on treatment with zosurabalpin, which can be in the form of itching, difficulty breathing, a rash, and/or drop in blood pressure.

2. Reactions due to the administration of the drug through a tube inserted into vein in participant's arm: symptoms may include chills, fever, nausea, headache, high or low blood pressure, fast heart rate, flushing, itching, and shortness of breath.

3. Reaction at the site of the injection: symptoms may include itchiness, pain, and redness.

Risks associated with study treatment administration:

The study treatment will be given through a PICC line that will be placed into a vein in the participant's arm and passed through to the larger veins near the participant's heart. The participant may experience a mild discomfort or sensation of warmth and pain during the procedure, and there is a small chance of infection from placing the needle into a vein in the arm.

There may be a risk in exposing an unborn child to the study treatment, 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 currently breastfeeding cannot take part in the study.

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

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