ForPatients
by Roche

Healthy Volunteers

A Phase I, randomized, double-blind, single ascending dose and multiple ascending dose study to evaluate the safety and pharmacokinetics of GDC-0829 in healthy subjects

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	1 Countries	GV44796

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 evaluate the safety and the processing of GDC-0829 by the body in healthy participants

F. Hoffmann-La Roche Ltd	Phase I
Sponsor	Phase

GV44796
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 65 years of age	Yes

Background and study aims:

The study drug GDC-0829 is an experimental drug being developed to treat infections. GDC-0829 being an experimental drug means that the health authorities have not approved it for the treatment of infections or any other disease. This is the first study where this drug will be tested in humans. The main aim of this study is to test GDC-0829 at different doses to find out if it is safe and to understand how the body processes the drug.

Who can participate?

Healthy volunteers between 18 and 65 years of age

What does the study involve?

This study will be conducted in two stages: the Single Ascending Dose (SAD) stage followed by the Multiple Ascending Dose (MAD) stage. Participants in the SAD stage will need to be a part of this study for 15 days and participants in MAD will need to be a part of this study for 38 days (excluding the screening period of 28 days). Both SAD and MAD stages will have three parts:

1. Screening Period: Tests would be done to determine if the participant is eligible to take part in this study. The screening period is 28 days.

2. Treatment Period:

SAD Stage: During this period participants will receive either GDC-0829 or a placebo, which looks like a drug but has no active ingredients. Participants will be assigned to GDC-0829 or placebo by chance (like tossing a coin). Participants will receive a single dose of GDC-0829 or placebo infusion into the vein (intravenous [IV] infusion). Participants will be required to check in to the clinic 2 days before receiving the study drug and will have to stay at the clinic for about 5 nights.

MAD Stage: Participants will receive a dose of GDC-0829 or placebo multiple times per day. Participants will be required to check in to the clinic 2 days before receiving the study drug and have to stay at the clinic for about 18 nights.

3. Follow-up Visits: After participants complete the treatment, they will have to return to the clinic for follow-up visits. Participants in the SAD stage will have two follow-up visits with the last visit taking place about 14 days after the dose of the study drug. Participants in the MAD stage will have four follow-up visits with the last visit taking place about 27 days after the last dose of the study drug.

What are the possible benefits and risks of participating?

Participants will not receive any benefit from participating in this study, but the information that is learned may help people with infections in the future.

Participants may have side effects from GDC-0829 or procedures used in this study. These can be mild to severe and even life-threatening, and they can vary from person to person. GDC-0829 has not yet been tested in humans and thus side effects are not known at this time. The potential side effects are listed below:

1. Allergic reactions due to administration of the drug, which can be in the form of fever, chills, itching, difficulty breathing, a rash, and/or a drop in blood pressure.

2. There may be a decrease in kidney function.

3. There may be temporary loss of muscle coordination including awkward, uncoordinated walking or unsteadiness when walking.

4. There may be a reaction at the site where the drug was injected into the vein.

5. There may be damage to the liver.

Where is the study run from?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

global-roche-genentech-trials@gene.com