

Infectious Diseases

A phase I, randomized, double-blind, multiple-ascending-dose study to evaluate the safety and pharmacokinetics of GDC-5780 in healthy subjects

Trial Status
Recruiting

Trial Runs In
1 Countries

Trial Identifier
GV44359

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 the safety and processing by the body of GDC-5780 in healthy participants

F. Hoffmann-La Roche Ltd (USA)
Sponsor

Phase 1
Phase

GV44359
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
18 to 65 years

Healthy Volunteers
Yes

Background and study aims GDC-5780 is an experimental drug, being developed to treat infections, which means health authorities have not approved it for the treatment of any disease. The purpose of this study is to test GDC-5780 at different doses to find out if it is safe and to understand the way the body will process the drug (pharmacokinetics).

Who can participate?

Healthy participants aged between 18 to 65 years old

What does the study involve? Participants will need to be a part of this study for about 40 days after the screening. The study will have three parts:

- A screening period when potential participants will be screened for eligibility to participate in the study
- A treatment period when participants will be required to check in to the clinic 2 days prior to treatment initiation and to remain in the clinic for about 18 nights (Day -2 up to Day 17)

ForPatients

by Roche

Participants will be randomly assigned in a 3:1 ratio to receive either GDC-5780 or a substance that looks like a drug but has no active ingredient (placebo). They will receive GDC-5780 or a placebo through the vein (intravenous infusion) multiple times per day.
- A follow-up visit after participants complete the treatment. Participants will have to return to the clinic for four follow-up visits.

What are the possible benefits and risks of participating?

The 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 the drug or procedures used in this study, they can be mild to severe and even life-threatening, and they can vary from person to person.

Risks associated with GDC-5780:

GDC-5780 has had limited testing in humans and all the side effects are not known at this time. Potential side effects include reactions during or following the drug infusion that may mimic an allergic reaction which could include symptoms such as fever, chills, rash, itching, low blood pressure, difficulty breathing, dizziness and headache. Other side effects could include a decrease in kidney function, awkwardness, uncoordinated or unsteadiness when walking (transient loss of muscle coordination).

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