ISRCTN15259645 https://doi.org/10.1186/ISRCTN15259645

A study to assess the safety and processing by the body of GDC-5780 in healthy participants

Submission date 02/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/03/2023	**Overall study status** Completed	
Last Edited 04/12/2023	**Condition category** Other	

Plain English summary of protocol

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)
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)

When is the study starting and how long is it expected to run for?
December 2022 to December 2023

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
GV44359

Study information

Scientific Title

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

Study objectives
The purpose of the study is to assess the safety and pharmacokinetics (PK) of multiple doses of GDC-5780 in healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/01/2023, WCG IRB (1019 39th Ave., SE Suite 120, Puyallup, WA 98374; +1-855-818-2289; clientcare@wcgirb.com), ref: 20230148

Study design
Phase I randomized participant- and investigator-blind placebo-controlled multiple-ascending-dose study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Randomization
A Block randomization method is used to generate a master randomization list. The sentinel subjects and remainder subjects are randomized separately, where the sentinel subjects have a 2:1 randomization ratio of GDC-5780 to placebo with a block size of 3, and the remaining subjects have a 4:1 randomization ratio of GDC-5780 to placebo with a block size of 5.

Participants will need to be a part of this study for about 40 days after the screening. The study will have three parts:
- Screening Period: Potential participants will be screened to check if they are eligible to participate in the study. The screening visit will take place up to 28 days before the study starts.
- Treatment Period: During this period participants will be required to check in to the clinic 2 days prior to treatment initiation. The participants will have to remain in the clinic for about 18 nights (Day -2 up to Day 17). Participants in each cohort will receive GDC-5780 or a GDC-5780 matched placebo as intravenous (IV) infusion multiple times per day for 10 days at escalating doses. Based on the safety data and the decision of the safety monitoring committee (SMC), participants may be enrolled in further cohorts to receive GDC-5780.
- Follow-up visit: Follow-up visits will be conducted to check on the participants after they complete the treatment. Participants will have to return to the clinic for four follow-up visits, with the last visit taking place about 28 days after the final dose of the study drug i.e., on Days 20, 24, 31, and 38.

Please note, the doses for each cohort are subject to change depending on the pharmacokinetics and/or safety/tolerability of GDC-5780, and therefore we would prefer that the doses are not included in the registry.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
GDC-5780

Primary outcome(s)
1. Incidence and severity of adverse events (AEs), with severity determined according to the Division of AIDS (DAIDS) toxicity grading scale and a modified Common Terminology Criteria for Adverse Events (CTCAE) grading scale for infusion related reactions, measured using data from electronic Case Report Forms (eCRFs) from initiation of the study up to Day 38
2. Incidence and severity of vital sign, laboratory test, and electrocardiogram (ECG) abnormalities measured using data from vital signs recorded (respiratory rate, pulse rate, systolic and diastolic blood pressure, and temperature), laboratory test results (serum/plasma /urine samples), and ECG readings (single 12-lead ECG recordings) from initiation of study to 28 days after the last dose (up to Day 38).

Key secondary outcome(s))
1. Maximum plasma concentration (Cmax) of GDC-5780 measured using plasma samples collected at multiple timepoints post-dose on Day 1
2. Maximum plasma concentration at steady state (Cmax,ss) of GDC-5780 measured using plasma samples collected at multiple timepoints post-dose on Day 10
3. Time to maximum observed concentration (tmax) of GDC-5780 measured using plasma samples collected at multiple timepoints post-dose on Day 1
4. Area under the concentration-time curve from time 0 to τ (AUC0- τ) of GDC-5780 measured using plasma samples collected at multiple timepoints post-dose on Day 1
5. Area under the concentration-time curve at steady state (AUC0- τ,ss) of GDC-5780 measured using plasma samples collected at multiple timepoints post-dose on Day 10
6. Lowest plasma concentration prior to next dose (Ctrough) of GDC-5780 measured using plasma samples collected prior to first infusion on Days 2-9
7. Terminal half-life (t1/2) of GDC-5780 measured using plasma samples collected at multiple timepoints post-dose from Day 10 up to Day 24
8. Fractional excretion (Fe) of GDC-5780 measured using pooled urine samples collected at post-dose timepoints on Day 10
9. Renal clearance (CLr) of GDC-5780 measured using pooled urine samples collected at post-dose timepoints on Day 10

Completion date
08/12/2023

Eligibility

Key inclusion criteria

1. Age 18 - 65 years at time of signing informed consent form (ICF)
2. Body mass index (BMI) of ≥ 18.5 and < 30 kilograms per metre squared (kg/m^2) at screening
3. Ability to comply with study protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 28 days after the final dose of study drug
2. Planned procedure or surgery during the study
3. Positive human immunodeficiency virus (HIV) test at screening
4. Positive hepatitis B surface antigen (HBsAg) test at screening
5. Positive hepatitis C virus (HCV) antibody test at screening
6. Any serious medical condition or abnormality in clinical laboratory tests
7. History of malignancy within 5 years prior to screening
8. Acute illness within 14 days prior to screening
9. Vaccination within 14 days prior to initiation of study drug

Date of first enrolment
08/03/2023

Date of final enrolment
30/10/2023

Locations

Countries of recruitment
United States of America

Study participating centre
ICON
United States of America
66219

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes