

Cardiovascular Disease

Is it safe for people to take a new medicine (GDC-2394) – and how is the medicine is processed by the body

Trial Status
Terminated

Trial Runs In
1 Country

Trial Identifier
GC42880

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Phase I, randomized, double-blind, placebo-controlled, dose-escalation study to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending oral doses of GDC-2394, the effect of food on the pharmacokinetics of GDC-2394, and the effects of GDC-2394 on midazolam pharmacokinetics in healthy volunteers

Trial Summary:

This phase 1 clinical trial was done to study a new medicine called, “GDC-2394”, for the treatment of patients with heart disease. The people who took part in this trial did not have any health issues. This study was done to find out if it was safe for people to get single (one day) and multiple (one week) treatments of GDC-2394 at different dose levels. Researchers also wanted to know the effect of food on GDC-2394, and whether GDC-2394 affected the way another medicine was processed by the body. Sixty-seven healthy people took part in this study at one study center in one country.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 1
Sponsor	Phase

GC42880
Trial Identifiers

Eligibility Criteria:

Gender Male and female	Age 18 to 65 years old	Healthy Volunteers Yes
----------------------------------	----------------------------------	----------------------------------

Healthy volunteers were enrolled at one study site in New Zealand to evaluate the safety and tolerability of GDC-2394, an NLRP3 inhibitor. Sixty-seven participants enrolled in

ForPatients

by Roche

the phase 1, placebo-controlled and randomized, double-blind, dose-escalation study. Results showed that the concentration of GDC-2394 in the body increased when the dose taken was increased. There was not much difference in the concentration whether taken with food or on an empty stomach. GDC-2394 did not affect how a second medicine (midazolam) was processed by the body. Two of 67 people (3%) experienced serious side effects that the doctors believed to be related to GDC-2394. These side effects eventually resolved. This study was stopped and nobody was allowed any more GDC-2394 because of these serious side effects.