

Healthy Volunteers

A study to find out how safe is it to give people a new medicine for asthma (GDC-4379), and to see how this medicine is processed in the body

Phase 1 study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of inhaled GDC-4379 conducted in three parts: A single-ascending dose study in healthy volunteers, a multiple-ascending dose study in healthy volunteers, and a proof-of-activity study in patients with mild asthma

Trial Status
Completed

Trial Runs In
1 Country

Trial Identifier
GA41024

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 1 study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of inhaled GDC-4379 conducted in three parts: A single-ascending dose study in healthy volunteers, a multiple-ascending dose study in healthy volunteers, and a proof-of-activity study in patients with mild asthma

Trial Summary:

Healthy volunteers for Parts A ($n=48$) and B ($n=32$), and asthma patients for Part C ($n=48$) were enrolled at two study sites in New Zealand to evaluate the safety and tolerability of GDC-4379, an inhibitor of JAK1. Part A was a single-ascending dose study (1–80 mg of GDC-4379). Parts B was a multiple-ascending dose study (3–80 mg QD). Part C was a proof of activity study (10–80 mg QD). Results showed GDC-0214 to be similarly tolerated in active and placebo dose groups. There were no deaths or serious side effects. One participant (Part B) stopped treatment due to a side effect. GDC-4379 showed some activity in reducing inflammation in patients with asthma. Based on this study, researchers decided not to develop GDC-4379 any further because the results showed that patients will need a very high dose of this medicine to control asthma.

GA41024
Trial Identifiers

Eligibility Criteria:

ForPatients

by Roche

Gender

All

Age

18 to 65 years

Healthy Volunteers

Yes

This clinical trial was done to study a new medicine called, “GDC-4379”, for the treatment of asthma. This study investigated whether it was safe to give people single and multiple doses of GDC-4379. Researchers also wanted to find out what happened to GDC-4379 in the body, and if there was any indication that GDC-4379 may be useful in patients with asthma. One hundred and twenty-eight healthy people and patients with asthma took part in this study at two study centers in one country.