ForPatients
by Roche

Asthma

A study of a new medicine for asthma and cough: GDC-6599, a TRPA1 inhibitor

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	2021-002464-48 GA43010

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:

A phase 1, randomized, double-blind, placebo-controlled, single-center study designed to evaluate the safety, pharmacokinetics, and pharmacodynamic effects of single and multiple ascending doses of GDC-6599 and the effect of food on the pharmacokinetics and pharmacodynamics of GDC-6599 in healthy adult subjects

Trial Summary:

This clinical trial was done to study a new medicine, “GDC-6599,” for the treatment of people with asthma. This study was done to look at side effects at different doses and learn about whether this medicine was safe and could be tolerated by people. Researchers also wanted to learn about the effect of food on this medicine and whether it had any effect on the cell structure it was targeting. This was a phase 1, placebo-controlled, randomized, double-blind, dose-escalation study that was conducted at one study center in the Netherlands.

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

2021-002464-48 GA43010
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 75 years	Yes

GDC-6599, a new TRPA1 inhibitor, is under development for the treatment of asthma and cough. This trial was conducted at a single study center in the Netherlands, involving

81 healthy volunteers. Some were given GDC-6599. Others were given a fake medicine (placebo) that did not have any real medicine in it. Results from the study showed no serious side effects. Thirteen people had non-serious side effects that doctors thought were related to the treatments.

Inclusion Criteria:

- Signed Informed Consent Form
- Age 18*75 years at time of signing Informed Consent Form
- Ability to comply with the study protocol, in the investigator*s judgment
- Body mass index of 18*30 kg/m2 at screening
- Veins suitable for venipuncture and/or cannula insertion to accommodate blood sample collection at multiple timepoints during the study

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 14 days after the final dose of study drug during the SAD/FE stage and for 28 days after the final dose of study drug during the MAD stage, unless a longer period is required by local regulations or ethics committee
- Women must have a negative serum pregnancy test result within 1 day prior to initiation of study drug.
- History of easy bruising or bleeding (i.e., bruising or bleeding out of proportion to the degree of trauma)
- Use of anticoagulant or anti-platelet therapies
- History of significant hepatic impairment, defined as Child-Pugh Class B or C, corresponding to a Child-Turcotte-Pugh Score >= 7
- History of abuse, in the investigator's judgment, of drugs including, but not limited to the following: amphetamines, barbiturates, benzodiazepines, cocaine, marijuana/cannabis, methadone, methamphetamine, ecstasy, morphine/opiates, phencyclidine, and tricyclic antidepressants within 12 months prior to screening and clinic admission
- A positive drug screen test for any of the drugs listed above at screening is exclusionary.