

Cancer - RET positive

How does the body process a cancer medicine (pralsetinib) – when it is taken together with another medicine (cyclosporine)

Trial Status
Completed

Trial Runs In
1 Country

Trial Identifier
GP43162

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, open-label, fixed-sequence study to evaluate the effect of a single dose of cyclosporine on the single dose pharmacokinetics of pralsetinib in healthy subjects

Trial Summary:

This clinical trial was done to study a medicine called, “pralsetinib”, for the treatment of patients with some types of cancer. The main questions were 1) What was the the effect of a single dose of cyclosporine on a single dose of pralsetinib? 2) How safe was it to give pralsetinib with cyclosporine – in comparison to giving pralsetinib alone? Fifteen healthy people took part in this study at one study center in one country.

F. Hoffmann-La Roche Ltd (Switzerland)
Sponsor

Phase 1
Phase

GP43162
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
18 to 55 years

Healthy Volunteers
Yes

Fifteen healthy volunteers were enrolled at one study site in USA to evaluate the effect of coadministration of cyclosporine on the pharmacokinetics of pralsetinib in healthy males and females of non-childbearing potential. Thirteen participants completed the study. Results showed that coadministration of cyclosporine and pralsetinib increased exposure to pralsetinib and increased the highest concentration of pralsetinib reached post-dosing.

ForPatients

by Roche

There were no deaths or serious side effects. The data from this study will help support further development of pralsetinib.