

Crohn's Disease

Afimkibart (RO7790121) for the Treatment of Moderate to Severe Active Crohn's Disease

Trial Status
Active, not recruiting

Trial Runs In
4 Countries

Trial Identifier
NCT05910528 2023-504265-23-00
GA45392

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 2, Multicenter, Double-blind, Two-arm Study of Subcutaneous RO7790121 for the Treatment of Subjects With Moderate to Severe Active Crohn's Disease

Trial Summary:

This Phase 2, randomized, double-blind, multicenter, induction and maintenance study is designed to evaluate the safety and efficacy of Afimkibart (RO7790121, RVT-3101) in adult participants with moderate to severe active Crohn's disease.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

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Eligibility Criteria:

Gender
All

Age
#18 Years & # 75 Years

Healthy Volunteers
No

Inclusion Criteria:

- Moderately to severely active CD as defined by CDAI and SES-CD, assessed by central read
- Elevated very soft or liquid stool frequency and/or abdominal pain
- Must have no response, insufficient response, loss of response and/or intolerance to at least 1 conventional therapy (e.g. corticosteroids) or advanced therapy

Exclusion Criteria:

ForPatients

by Roche

- Diagnosis of ulcerative colitis, indeterminate colitis, microscopic colitis, ischemic colitis, infectious colitis, radiation colitis or active diverticular disease
- Short gut syndrome
- Presence of an ostomy or ileoanal pouch
- Bowel resection or diversion with ~6-months