

Mild to severe ulcerative colitis

A Study to Evaluate the Pharmacokinetics, Safety and Efficacy of Afimkibart (RO7790121) in Children With Moderately to Severely Active Ulcerative Colitis

Trial Status
Recruiting

Trial Runs In
4 Countries

Trial Identifier
NCT07158242 2025-522518-22-00
CA45905

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 III Randomized Double-Blind Multi-Center Treat-Through Study to Evaluate the Pharmacokinetics, Safety and Efficacy of Induction and Maintenance Therapy With Afimkibart (RO7790121) in Children Aged 2 - 17 Years With Moderately to Severely Active Ulcerative Colitis

Trial Summary:

This Phase III, randomized, double-blind, multicenter, induction and maintenance study will evaluate the safety and efficacy of Afimkibart (RO7790121) in pediatric participants with moderate to severe active ulcerative colitis (UC).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#2 Years & # 17 Years

Healthy Volunteers
No

Inclusion Criteria:

- Bodyweight \geq 10 kilogram (kg)
- Confirmed diagnosis of UC

ForPatients

by Roche

- Demonstrated intolerance or inadequate response (IR) to one or more of the following categories of drugs: systemic corticosteroids, immunomodulators, and/or biologic therapies as outlined in the protocol

Exclusion Criteria:

- Monogenic disorder pertaining to infant onset inflammatory bowel disease (IBD)
- Current diagnosis of Crohn's disease (CD), abdominal/intrabdominal/perianal fistula and/or abscess, indeterminant colitis, IBD-unclassified, microscopic colitis, ischemic colitis, infectious colitis, radiation colitis, or active diverticular disease
- Presence of an ostomy or ileoanal pouch
- Current diagnosis or suspicion of primary sclerosing cholangitis
- Any major surgery within 6 weeks prior to screening or a major planned surgery during the study
- Active tuberculosis (TB) infection suggested by positive TB testing, clinical symptoms, and/or chest imaging (X-ray or CT)