ForPatients
by Roche

Mild to severe ulcerative collitis

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

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		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

NCT07158242 2025-522518-22-00 CA45905
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#2 Years & # 17 Years	No

Inclusion Criteria:

- Bodyweight >= 10 kilogram (kg)
- Confirmed diagnosis of UC

- 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)