ForPatients
by Roche

Autoimmune DisorderCrohn's Disease

A study to assess the effectiveness and safety of afimkibart for induction and maintenance therapy in children with moderately to severely active Crohn’s disease

A Study to Assess the Pharmacokinetics, Effectiveness and Safety of Afimkibart for Induction and Maintenance Therapy in Children With Moderately to Severely Active Crohn's Disease

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07298421 2025-523318-96-00 CP45906

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 Crohn's Disease

Trial Summary:

This phase III, double-blind, multi-center treat-through study will evaluate the efficacy and safety of Afimkibart (also known as RO7790121) in children with moderately to severely active Crohn's Disease (CD).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT07298421 2025-523318-96-00 CP45906
Trial Identifiers

Eligibility Criteria:

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

1. Why is this study needed?

Crohn's disease (CD) is a type of inflammatory bowel disease (IBD). It causes swelling of the tissues (inflammation) in the digestive tract, which can lead to stomach pain, severe diarrhoea, tiredness and weight loss. CD can range from mild to severe and may affect daily life. When people with CD have symptoms, it means their CD is ‘active’. Currently, only a few treatment options are available for children. There is still a need for new treatments for children with CD that can help reduce symptoms and keep them well in the long term.

This study is testing a medicine called afimkibart. It is being developed to treat moderately to severely active CD.

Afimkibart is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved afimkibart for the treatment of CD.

This study aims to see how safe and how well afimkibart works at different doses. It also looks at how it gets to different parts of the body, and how the body changes and gets rid of it in children with moderately to severely active CD.

2. Who can take part in the study?

Children (males/females) of 2 - 17 years of age with moderately to severely CD who weigh at least 10 kg can take part in the study. They must have an active CD confirmed by endoscopy. An endoscopy is a procedure where a doctor uses a flexible tube (called a scope) with a camera on one end to look inside the body. The child must also have taken at least 1 other medicine for CD that either didn’t work well, stopped working, or caused unacceptable unwanted effects.

Children may not be able to take part in this study if they have already had three surgeries to remove parts of the intestine or have an ostomy (an opening in the belly where waste passes into a bag). Children who have certain other medical conditions, such as ulcerative colitis or certain infections, also cannot take part. Those who are pregnant, trying to get pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

This study consists of a screening period, a treatment period of 1 year, an optional treatment extension period, and a safety follow-up period of 12 weeks.

Children will be screened to check if they are able to participate in the study. The screening period will take place up to 35 days before the start of treatment.

Everyone who joins this study will be split up into 4 groups randomly (like throwing a dice) based on their body weight (a lower body weight group, and a higher body weight group).

- Participants who are in the higher body weight group will have an equal chance of being placed in the low dose group (Group 1) or the high dose group (Group 2) of afimkibart.
- Participants who are in the lower body weight group will have an equal chance of being placed in the low dose group (Group 3) or the high dose group (Group 4) of afimkibart.

Participants will receive afimkibart, given as a drip into the vein (intravenous infusion) for the first four times. After this, it will be given as an injection under the skin (subcutaneous injection) for the rest of the study.

This is a double-blinded study. This means that neither the participants in the study nor the team running it will know which treatment is being given until the study is over. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

After completing the 1 year treatment period, if participants agree and the study doctor thinks it’s suitable, they can keep receiving treatment in an extension of the study. Everyone who joins the extension will be given afimkibart (higher dose) as an injection under the skin every few weeks. The extension is open-label. This means everyone involved, including the participant and the study doctor, will know the participant has been given the higher dose of afimkibart.

During this study, the study doctor will see participants every few weeks. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have 2 follow-up visits after 6 weeks and 12 weeks of completing the study treatment, during which the study doctor will check on the participant’s well being. Total time of participation in the study will be about 1.5 years (18 months) if not joining the optional extension phase. If they choose to join it, the study will last up to an additional 4 years. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked are

- The number of participants who have no or very few signs of CD 1 year after starting the study (PCDAI score 10 or less).
- The number of participants whose bowel shows more than 50% improvement on an endoscopy, 1 year after starting the study.

Other key results measured in the study include:

- The number of participants who have no or very few signs of CD 3 months after starting the study (PCDAI score 10 or less).
- Fecal calprotectin levels (a substance in stool that shows inflammation in the gut) at 3 months and 1 year
- The number of participants who have no or mild signs of CD at 1 year without using corticosteroids (medicines that reduce inflammation)
- The number and seriousness of unwanted effects

The pediatric Crohn's disease activity index, (PCDAI) is a scoring system doctors use to measure how severe CD symptoms are in children.

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicine
Participants may have unwanted effects of the medicine used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Afimkibart: Participants will be told about the known unwanted effects of afimkibart, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include allergic reactions, feeling sick and joint paint.

Known unwanted effects of infusion include pain, bruising, redness, warmth, burning, stinging or itching on the skin where it has been pricked with a needle to give a treatment. Known unwanted effects of injections under the skin include a reaction, swelling or rash on the skin where it has been pricked with a needle to give a treatment.

The study medicines may be harmful to an unborn baby. Female participants who can become pregnant must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Body weight >= 10 kilogram (kg)
- Active CD confirmed by endoscopy (ileocolonoscopy)
- Moderately to severely active CD, defined as a Pediatric Crohn's Disease Activity Index (PCDAI) score >= 30, and Simple Endoscopic Score Crohn's Disease (SES-CD) >=6 (or >=4 for isolated ileal disease) confirmed through centrally-read ileocolonoscopy
- Inadequate response, loss of response, and/or intolerance to at least one of the following conventional therapies (aminosalicylates, corticosteroids and/or immunosuppressants) or advanced therapies (including anti-tumor necrosis factor, anti-interleukin, anti-integrin, or Janus Kinase (JAK) inhibitors)

Exclusion Criteria:

- Monogenic disorder pertaining to infant onset Inflammatory Bowel Disease (IBD)
- History of >= 3 bowel resections: > 2 missing segments of the following five segments: terminal ileum, right colon, transverse colon, sigmoid and left colon, and rectum
- Current diagnosis of ulcerative colitis (UC), abdominal/intraabdominal/perianal fistula and/or abscess, indeterminant colitis, IBD-unclassified, microscopic colitis, ischemic colitis, infectious colitis, radiation colitis, or active diverticular disease.
- Symptomatic bowel strictures, fulminant colitis, or toxic megacolon
- Presence of abdominal or perianal abscess
- Current diagnosis or suspicion of primary sclerosing cholangitis