ForPatients
by Roche

Ulcerative ColitisMild to severe ulcerative collitis

A study to assess the effectiveness and safety of RO7790121 for induction and maintenance therapy in participants with moderately to severely active ulcerative colitis

A Study to Assess the Efficacy and Safety of RO7790121 for Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	30 Countries	NCT06589986 2024-513014-35-00 GA45329

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, Multicenter, Double-Blind, Placebo-Controlled, Treat-Through Study to Assess the Efficacy and Safety of Induction and Maintenance Therapy With RO7790121 in Patients With Moderately to Severely Active Ulcerative Colitis

Trial Summary:

This Phase III, multicenter, double-blind, placebo-controlled, treat-through study will evaluate the efficacy and safety of RO7790121 compared with placebo in participants with moderately to severely active ulcerative colitis (UC).

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

NCT06589986 2024-513014-35-00 GA45329
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#16 Years & # 80 Years	No

1. Why is this study needed?

Ulcerative colitis (UC) is a health issue that causes inflammation in the inside layer of some parts of the bowel. It often affects the rectum and the lower colon – also called

the large intestine. It can cause bleeding sores or mucus to form. This leads to frequent loose stools or bowel movements and bleeding from the rectum. When UC is ‘moderate to severe’, a person will have 6 to 10 urgent bowel movements per day that are sometimes bloody. When UC is ‘severe’, a person will have more than 10 urgent bloody bowel movements per day. When people with UC have symptoms, their UC is said to be ‘active’. People with moderately and severely active UC might also have pain in the belly, tiredness and weight loss.

Standard treatments for UC include medicines that reduce inflammation, such as corticosteroids, biologics and small molecules. But for many people living with UC, symptoms do not improve even with these treatments. Treatment can also stop working after a time or cause unacceptable unwanted effects that affect a person’s ability to continue on a therapy and function. So, better treatments for UC are needed.

This study is testing a medicine called RO7790121. It is also called afimkibart. Afimkibart is an investigational medicine being developed to treat UC. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved afimkibart for treating UC.

This study aims to compare the effects of afimkibart as long-term treatment against ‘placebo’. A placebo is a medicine that contains no active ingredients but looks the same as the study medicine. Researchers want to see if afimkibart works, how well it works and how safe it is when given over a long period of time. This is compared to a placebo in people living with moderately to severely active UC.

2. Who can take part in the study?

People aged 18 to 80 years old, and fully-developed 16 to 17 year olds in some countries, with moderately to severely active UC can take part in the study. Their UC diagnosis must have been confirmed by an ‘endoscopy’. An endoscopy is a procedure where a doctor uses a flexible tube with a camera on it to look inside the large intestine (colon). To take part, people also must have taken at least 1 other medicine for UC that didn’t work very well, stopped working or caused unacceptable unwanted effects.

People cannot take part in this study if they have severe UC that requires a hospital stay for treatment, such as surgery. People who have certain other medical conditions, such as Crohn’s disease, abnormal cells in their bowel (known as ‘dysplasia’), some types of cancer within the last 5 years, or certain infections also cannot take part. People who are trying to get pregnant, plan to get pregnant, plan to donate eggs or sperm or are 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. Participants will be screened to check if they are able to participate in the study. This is a ‘placebo-controlled’ study. This means that participants are put in a group that will receive a medicine or a group that will receive placebo. Comparing results from the different groups helps researchers know if any changes seen result from the study medicine or occur by chance.

Everyone who joins this study will be placed into 1 of 2 groups randomly. Participants will be given either afimkibart OR a placebo, given as a drip into a vein (known as an infusion). Then participants will then be given afimkibart or placebo as an injection under the skin until they have had treatment for 1 year.

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. If participants agree and the study doctor thinks it's suitable, they can keep receiving treatment in an extension of the study. They must have completed at least 3 months of study treatment. Everyone who joins the extension will be given afimkibart. The extension is open-label. This means everyone involved, including the participant and the study doctor, will know the participant has been given afimkibart.

During this part of the study, the study doctor will see participants regularly. Some visits may take place in the participant’s home by a nurse if they prefer. The study doctor 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 3 months of completing the study treatment, during which the study doctor will check on the participant’s wellbeing. Total time of participation in the study could be up to 5 years if they take part in the extension of the study. 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 result measured in the study to assess if the medicine has worked is the number of participants who have no or very few signs of UC after 3 months and 1 year of beginning the study.

Other key results measured in the study include:

- The average number of bowel movements per day and amount of bleeding from the rectum after 2 weeks of treatment compared to the start of the study

- The number of participants who have: fewer or no bleeding sores, less or no mucus, and reduced signs of inflammation, in the large intestine at 3 months and 1 year. This is assessed with an endoscopy
- The number of participants who have at least a 30% reduction in signs of UC (number of bowel movements per day, amount of bleeding and endoscopy results) at 3 months
- The number of participants who have no or few signs of UC at 1 year and who have not taken corticosteroids for at least 2 months
- How much participants report their UC symptoms have changed and how severe symptoms are
- The number and seriousness of unwanted effects.

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 drug Participants may have unwanted effects of the drug 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
Afimkibart has had limited testing in humans. The potential unwanted effects of this medicine are based on human and laboratory studies, or knowledge of similar medicines. These include allergic reactions, feeling sick and joint pain. There might be other unwanted effects that are not known at this time. Known unwanted effects of infusions include pain, bruising, redness, warmth, burning, stinging or itching on the skin where it has been pricked with a needle to give a treatment. Other unwanted effects of infusions can include throwing up, wanting to throw up, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, pain or discomfort in the head. 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 medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Confirmed diagnosis of UC
- Moderately to severely active UC assessed by mMS
- Bodyweight >= 40 kilogram (kg)
- Up to date with colorectal cancer (CRC) screening performed according to local standards
- Demonstrated inadequate response, loss of response and/or intolerance to at least one protocol-specified conventional or advanced UC therapy
- Males and females of childbearing potential must meet protocol criteria for contraception requirements

Exclusion Criteria:

- Currently known complications of UC (e.g. fulminant colitis, toxic megacolon)
- Current diagnosis of Crohn's disease (CD) or indeterminate colitis, microscopic colitis, ischemic colitis, infectious colitis, radiation colitis
- Presence of an ostomy or ileoanal pouch
- Current diagnosis or suspicion of primary sclerosing cholangitis
- Pregnancy or breastfeeding, or intention of becoming pregnant during the study
- Past or current evidence of definite low-grade or high-grade colonic dysplasia or adenomas or neoplasia not completely removed
- History of malignancy within 5 years, with the exception of malignancies adequately treated with resection for non-metastatic basal cell or squamous cell cancer or in situ cervical cancer
- Evidence of infection with Clostridioides difficile (C. difficile; formerly known as Clostridium difficile), cytomegalovirus (CMV), human immunodeficiency virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV)
- Has evidence of active tuberculosis (TB), latent TB not successfully treated (per local guidance) or inadequately treated TB
- Has received protocol-specified prohibited medicines, including known exposure to any type of anti-TL1A therapy