ForPatients
by Roche

Crohn's Disease

A study to assess the effectiveness and safety of induction therapy with RO7790121 in participants with moderately to severely active Crohn's disease

A Study to Assess the Efficacy and Safety of Induction Therapy With Afimkibart (RO7790121) in Participants With Moderately to Severely Active Crohn's Disease

Trial Status	Trial Runs In	Trial Identifier
Recruiting	27 Countries	NCT06819891 2024-513054-30-00 GA45332

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase III, Multicenter, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Induction Therapy With RO7790121 in Patients With Moderately to Severely Active Crohn's Disease

Trial Summary:

This Phase III, multicenter, double-blind, placebo-controlled study will evaluate the efficacy and safety of induction therapy with Afimkibart (also known as RO7790121) in participants with moderately to severely active Crohn's disease (CD).

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

NCT06819891 2024-513054-30-00 GA45332
Trial Identifiers

Eligibility Criteria:

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

1. Why is this study needed?

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Crohn's disease (CD) is a type of inflammatory bowel disease. It causes chronic inflammation of the tissues in the digestive tract. When people with CD have symptoms, their Crohn's is said to be 'active'. People with 'moderately to severely active' CD can have symptoms such as feeling tired or weak, belly pain, frequent loose or watery stools (diarrhoea), weight loss, and fever. Standard treatments for CD include medicines that reduce inflammation, such as corticosteroids, biologics and small molecules. But for many people living with CD, symptoms do not improve even with these treatments. Treatment can also stop working after a time or cause unacceptable and unwanted effects that affect a person's ability to continue receiving their medicine. So, better treatments are needed.

This study is testing a medicine called Afimkibart (previously known as 'RO7790121' or 'PF-06480605' or 'RVT-3101'). Afimkibart is an investigational medicine being developed to treat CD. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not yet approved RO7790121 for treating CD.

This study aims to compare afimkibart with a '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. In this study, patients will get either afimkibart.

2. Who can take part in the study?

People aged 18 to 80 years old, with moderately to severely active CD can take part in the study. Their CD 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 CD that didn't work very well, stopped working or caused unacceptable unwanted effects.

People cannot take part in this study if they have had 3 or more surgeries to remove part of the intestines or they are taking certain medicines for CD. People who have certain other medical conditions such as ulcerative colitis, abnormal cells in their bowel (known as 'dysplasia'), some types of cancer within the last 5 years, or certain infections such as HIV, hepatitis B, hepatitis C, or tuberculosis also cannot take part. People who are pregnant, planning to get pregnant, planning 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 called 'induction therapy', an optional treatment extension period and a safety follow up period. People 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

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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 and be given afimkibart OR placebo. All participants may continue to take their usual anti-inflammatory treatment for CD as well as the study treatment.

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 expect from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

During this study, the study doctor will see participants regularly. The study doctor will see how well the treatment is working and any unwanted effects participants may have. If participants complete the induction therapy phase and the study doctor thinks it's suitable, they can agree to keep receiving treatment in an open-label extension phase of the study. Open-label means everyone involved, including the participant and the study doctor, will know the participant has been given afimkibart. Some visits may take place in the participant’s home by a nurse if they prefer. If CD gets worse during the extension, afimkibart may be given more frequently. Treatment will continue until afimkibart is commercially available in that region or until the Sponsor decides to terminate the study, whichever is earlier. 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 is the number of participants with no or very few signs of CD or improvements in intestine health (such as fewer and smaller ulcers) Other key results measured in the study include:

- The number of participants with no or improved signs or symptoms of CD. This includes: the average number of bowel movements per day and the average daily belly pain score. It also includes improvements in the health of their intestines.
- The number of participants with no ulcers.
- The number of participants with a passageway, called a ‘fistula’, between the intestines and the exterior of the body
- How much participants report their CD 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?

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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 has had limited testing in humans. 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 pain.

Known unwanted effects of treatment administration 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 and reaction on the skin where it has been pricked with a needle to give a treatment. There may be a risk in exposing an unborn child to study medication, as all the risks are not known at this time. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Confirmed diagnosis of CD
- Moderately to severely active CD
- Bodyweight >= 40 kilogram (kg)
- Demonstrated inadequate response, loss of response and/or intolerance to at least one protocol-specified conventional or advanced CD therapy
- Males and females of childbearing potential must meet protocol criteria for contraception requirements

Exclusion Criteria:

- Current diagnosis of ulcerative colitis (UC) or indeterminate colitis, ischemic colitis, infectious colitis, radiation colitis, microscopic colitis
- Participant with a history of >= 3 bowel resections (> 2 missing segments of the 5 following segments: terminal ilelium, right colon, transverse colon, sigmoid and left colon, and rectum)
- Diagnosis of short gut or short bowel syndrome
- Presence of an ileostomy, colostomy or ileoanal pouch
- Participants with symptomatic bowel strictures, fulminant colitis, or toxic megacolon

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- Presence of abdominal or perianal abscess
- Presence of rectovaginal, enterovaginal, high output enterocutaneous fistula, enterovesical fistulas or perianal fistulas with >3 openings
- Participants with symptomatic bowel strictures, fulminant colitis, or toxic megacolon
- Current diagnosis or suspicion of primary sclerosing cholangitis
- Pregnancy or breastfeeding, or intention of becoming pregnant during the study
- Any past or current evidence of cancer of gastrointestinal tract, high-grade colonic dysplasia and participants with low-grade dysplasia are eligible if lesions have been completely removed
- History of non-gastrointestinal cancer, with the exception of adequately treated non-metastatic basal cell or squamous cell skin 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) during screening
- 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

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