ForPatients
by Roche

Crohn's Disease

A study to look at different doses and side effects of a new medicine - zinpentraxin alfa - in healthy people

A Phase Ia, Randomized, Investigator- and Subject-Blinded, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single-Ascending Doses of RO7490677 in Healthy Volunteers

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	GP44089

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This clinical trial investigated a new medicine called “zinpentraxin alfa” for the treatment of “fibrostenotic Crohn's disease.” Healthy people joined this study to find out if zinpentraxin alfa was safe to give to people – based on side effects seen at the doses tested. People were randomized to receive a single treatment of zinpentraxin alfa or a placebo, through an IV. Each new group got a higher dose if it was safe to increase the dose. This was a double-blind, ascending dose, Phase 1 study. Study doctors noted the nature, frequency, and severity of side effects.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland) Sponsor	**Phase 1** Phase

GP44089
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 65 years	Yes

Background and study aim:

Healthy volunteers were enrolled at one study center in the USA to evaluate the safety and tolerability of zinpentraxin alfa, a medicine for fibrostenotic Crohn's disease. Sixteen people completed this study. Two doses were tested and found to be safely tolerated.

There were no serious side effects. Common side effects of infusion-related reaction were seen after placebo treatment in one person and zinpentraxin alfa treatment in another person.

Inflammatory bowel disease (IBD) is a type of inherited disorder that causes frequent pain and swelling (inflammation) of the intestines. The cause of IBD remains unknown, however environmental factors may trigger inflammation. IBD includes two related diseases, Ulcerative Colitis (UC) and Crohn's Disease (CD). Fibrostenotic Crohn’s disease (FCD) is a subtype of CD in which chronic or long-term inflammation of the digestive tract (gastrointestinal tract; GI) is observed. Zinpentraxin alfa (also called RO7490677) increases the regulatory capacity of a protein called pentraxin-2 (PTX-2) thus promoting healing and reducing scarring (fibrosis). It is an experimental drug, which means health authorities have not approved Zinpentraxin alfa (RO7490677) for the treatment of any disease. It has previously been tested in healthy volunteers and in participants with disease causing scar tissue built up in the lungs (idiopathic pulmonary fibrosis) and an uncommon type of bone marrow cancer (myelofibrosis).

The main purpose of this study is-

1. To test the drug at different doses to find out if it is safe

2. To understand the way body processes the drug

Who can participate?

Health Volunteers with age between 18 years and 65 years.

What does the study involve?

The maximum length of participation in the study, once enrolled, will be up to 1 month. The study involves three parts: -

1. Screening (to see if the participants are eligible for the study): The participants will be asked to complete some procedures and tests, including blood and urine tests, to check their eligibility. They might be asked to come back for further visits for confirmation.

2. Residential Phase (where the participants will receive treatment and stay in the clinic, for assessments): The participants will receive one infusion into the vein (intravenous) of zinpentraxin alfa (RO7490677) or medicine that looks like a drug but has no active medicinal ingredients (placebo) the day after they check in at the study site. The infusion will take about an hour. The participants will be required to check in to the study site 1 day before they receive the study drug, and the stay at the clinic will be for about 9 nights.

3. Follow-up (to check on the participant after treatment is finished): The participants will return to the study site for a follow-up visit (lasting about 2 hours) about 20 days after they check out.

Participants will be enrolled in to receive either infusion of zinpentraxin alfa (RO7490677) or placebo on Day 1. The treatment (zinpentraxin alfa or placebo) will be decided by chance (like tossing a coin). The participant will have a one in four chance of getting placebo. Neither participant nor the study doctor can choose or know the group the participant is in.

What are the possible benefits and risks of participating?

Participants will not receive any direct medical benefit from participating in this study, but the information will help other people with diseases such as fibrostenotic Crohn's disease in the future. Participants will also receive monetary compensation as outlined in the consent form depending upon clinic visits and follow-up visits. Participants may have side effects from the drugs or procedures used in this study that are mild to severe and even life-threatening, and they can vary from person to person. Zinpentraxin alfa (RO7490677) has had limited testing in humans. The potential side effects based on human and laboratory studies or knowledge of similar drugs, are listed below. There may be side effects that are not known at this time.

- Fever
- Chills
- Dizziness
- Rash
- Headache
- Nausea (feeling of sickness in your stomach)
- Vomiting
- Anaphylaxis or hypersensitivity (allergic reaction): Anaphylaxis is a serious, potentially life-threatening allergic reaction requiring immediate medical treatment by your doctor. The reaction may cause hives on the skin, itchiness of the skin, extremely low blood pressure, swelling of the throat, difficulty breathing, and loss of consciousness
- Immune system might develop special proteins in the body that respond to a substance that is foreign to the body (antibodies) to zinpentraxin alfa (RO7490677) (the study drug)
- Tiredness (fatigue)
- Cough
- Common cold (nasopharyngitis)
- Worsening of illness where the lungs become scarred and breathing becomes difficult (idiopathic pulmonary fibrosis)
- Loose, watery, and more frequent bowel movements (diarrhoea)
- Swelling in the tubes that carry air in the lungs (bronchitis)
- Joint stiffness (arthralgia)

- Pain in the stomach area (Abdominal pain)

There may be some risks associated with the procedures performed during the study:

- For blood samples - Drawing blood can cause pain, bruising, or infection where the needle is inserted. Some people experience dizziness, fainting, or upset stomach when their blood is drawn.

There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to study drug. If participants are pregnant, become pregnant, or are currently breastfeeding, participants cannot take part in this study.