ForPatients
by Roche

Idiopathic Pulmonary Fibrosis (IPF)

A study to look at two generations of a medicine (zinpentraxin alfa) – that were manufactured in two different ways – how do they move through the body, from absorption to elimination

A Phase 1 Double-Blind, Randomized, Two-Arm, Two-Way Crossover, Sequential Two-Stage Study to Assess the Pharmacokinetic Comparability of First and Second Generation RO7490677 (Recombinant Human Pentraxin-2; rhPTX-2) Drug Products in Healthy Subjects

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Countries	GP44111

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 was done to study a new medicine called, “zinpentraxin alfa,” that is being developed for the treatment of a type of lung disease (idiopathic pulmonary fibrosis). This study was done to compare two different manufacturing processes that produced the 1st and 2nd generation zinpentraxin alfa. This was a Phase 1, double-blind, randomized, two-arm, two-way crossover, sequential two-stage study. This study took place at one study center in one country – the USA.

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

GP44111
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	Between 18 and 70 years	Yes

This study took place at one study center in the USA to evaluate the pharmacokinetics of 1st and 2nd generation zinpentraxin alfa, that differed in the way they were manufactured. Forty-four healthy volunteers were enrolled before the sponsor decided to stop further development of the study medicine. People were randomized into two groups. One group

received 1st followed by 2nd generation. The other group received 2nd followed by 1st generation. There was a 7-day period in-between dosing so that the first dose became undetectable before the second dose was given. Researchers found some similarities and some differences in the pharmacokinetics measurements for the 1st and 2nd generation zinpentraxin alfa.

Background and study aims:

The study drug (RO7490677) is an experimental drug being studied in patients with Idiopathic pulmonary fibrosis (IPF). It has not been approved by health authorities.

The purpose of this study is to look at how much of the study drug gets into the blood stream (and so can have an active effect) and how long it takes the body to get rid of it when given as single doses of two different formulations (1st generation study drug compared to 2nd generation study drug) seven days apart. The safety and tolerability of the study drug will be evaluated, and information about any side effects that may occur will also be collected. In addition, the response of the participants body's natural defences (immune system's) to the study drug will be evaluated.

Who can participate?

Healthy volunteers who are between 18 and 70 years of age, both inclusive, can participate.

What does the study involve?

Participants will be a part of this study for a maximum of 7 weeks.

This study will be conducted in three parts:

1. Screening Period: Participants will have to undergo certain test to see if they are eligible to participate in the study. There will be one screening visit 5 weeks before start of the study

2. Treatment Period: Participants will be asked to reach the clinic one day prior to dosing to begin the in-clinic stay. They will be asked to stay at the research unit for approximately 16 days/15 nights. Few tests will be performed prior to dosing. The participant will be dosed with either 1st generation or 2nd generation of the test drug on Day 1 and the other formulation on Day 8.

The order in which the participant receives the formulations (1st or 2nd generation) will be determined by chance, like flipping a coin. There will be a time in which no dosing is given t (washout period) of 7 days between each dosing.

What are the possible benefits and risks of participating?

Participation in this study is purely for research purposes and will not improve the participant's health or treat any medical problem they may have. The participants may benefit by having physical examinations in which the results of laboratory tests done will be made available upon request. Participants will receive a compensation of up to $5,680.00 for taking part in this research study. RO7490677 is an experimental drug and has had limited testing in humans. There may be side effects that are not known at this time. The potential side effects of this drug are listed below:

• Infusion-Related Reaction: Symptoms may include fever, chills, dizziness (caused by low blood pressure), rash, headache, nausea, or vomiting.

• Anaphylaxis or Hypersensitivity: Allergic reactions can happen with any drug. These can be in the form of hives on the skin, itchiness of the skin, extremely low blood pressure or dizziness, swelling of the throat, difficulty breathing, or loss of consciousness

• Immunogenicity: There is a chance that the immune system might develop special antibodies (proteins made in the body that respond to a substance that is foreign to the body) to this study drug.

• Pregnancy Risk: No humans have become pregnant while being treated with RO7490677, so it is unknown whether this is a risk for humans

• The most common side effects were tiredness (fatigue) and headache.

• Few other side effects were cough, common cold (nasopharyngitis), worsening of idiopathic pulmonary fibrosis, diarrhea, and inflammation of the airways (bronchitis)

• Side effects seen in more than 10% of patients were tiredness (fatigue), cough, diarrhea, nausea, joint stiffness (arthralgia), headache, and abdominal pain

There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time.