ForPatients
by Roche

Healthy Volunteers

A study to find out if blood sampling techniques used in clinical trials can be replaced with better options

An open-label, parallel-group study to compare low-volume blood sampling techniques versus conventional venipuncture for the assessment of pharmacokinetic profiles of a single dose of various study drugs in healthy subjects

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	GE43429

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

Trial Summary:

People were given different medicines. Blood samples were collected using different methods. The amount of medicine in each blood sample was compared to that in the blood sample collected using the method of puncturing a hole in the vein (venipuncture). This study was done to find out how other blood sampling methods compared to venipuncture. Healthy people took part in this study. They got a medicine called “giredestrant” which is being studied for the treatment of a type of breast cancer. They also got 3 other medicines. This study took place at one study center in one country – the USA.

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

GE43429
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 65 years	Yes

Healthy volunteers were enrolled at one study site in one country (USA) to compare how different blood sampling methods affected medicine measurements in blood. Forty people took part in this study. This was an open-label, parallel-group study to compare low-volume blood sampling techniques to venipuncture for assessing the pharmacokinetics of a single dose of various medicines given to healthy people. Results showed that the

old and new blood sampling techniques gave similar results – so long as a mathematical calculation was used to account for differences due to the different sampling techniques. Nobody in this study had a serious side effect. Nobody stopped the study because of side effects.

Who can participate?
People aged between 18 to 65 years who are healthy

What does the study involve? This study has three parts:

- Screening (to see if people are eligible for the study)
- Check-in and treatment
- Follow-up (to check after treatment is finished)

During this study, there will be up to nine visits. The first visit may last 3 days and later visits may last 3 hours. The total time in the study will be up to about 4.5 months.

What are the possible benefits and risks of participating?
Participants will not receive any benefit from participating in this study but the information that is learned may help patients with certain diseases or conditions in clinical trials in the future.

There may be side effects from the drug or procedures used in this study, which can be mild to severe and even life-threatening, and they can vary from person to person. The study doctor will assess right away if participants have any of the following during the study:

- Symptoms that are new or have worsened
- Changes in prescribed or over-the-counter medications (including herbal therapies)
- Visits to the doctor or hospital, including urgent care or emergency room visits

There may be a risk in exposing an unborn child to the study drug and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to the study drug. If participants are pregnant, become pregnant, or are currently breastfeeding, one cannot take part in this study. As is true for any experimental drug, there may be unknown and potentially serious or life-threatening side effects, infusion-related injuries or death. These adverse events (side effects) listed in the table below were reported in previous studies from patients who received more than one dose of the study drug.

Crenezumab is an experimental drug that is being studied as a potential treatment for patients with Alzheimer’s disease, a brain disease that causes problems with memory, behavior, and thinking ability. Subjects may experience side effects from the drug or procedures in this study. Side effects can vary from mild to very serious and may be different from person to person. The majority of side effects identified in studies are from

observations following dosing over an extended period and are not likely to occur with administration of only one dose of crenezumab. Risks associated with crenezumab include allergic reactions such as itching, difficulty breathing, rash and/or drop in blood pressure; pneumonia, local reactions at site of infusion/injection. There is also a rare risk of death.

Giredestrant is still being studied, and the side effect profile is not completely known. So far, the known side effects appear to be mild to moderate in severity with no known serious risks. The vast majority of these side effects resolved without the need for treatment or interruption of giredestrant. It is also possible that subjects might experience side effects that are unknown at this time. As is true for any experimental drug, there may be unknown and potentially serious or life-threatening side effects, including death, that could occur with giredestrant. However, the majority of side effects identified in studies are from observations following dosing over an extended period and are not likely to occur with only one dose of giredestrant. Common side effects observed with giredestrant include joint pain, diarrhea, dizziness, fatigue, muscle and/or bone pain, nausea, hot flushes and vomiting.

Etrolizumab is still being studied, and the side effect profile is not completely known. The majority of side effects identified in studies are from observations following dosing over an extended period and are not likely to occur with only one dose of etrolizumab. The very common side effects include joint ache, fatigue, rash, common cold and uncommon side effects are skin inflammation, rash with the presence of flat discolored area, appendicitis.

Hydroxychloroquine has well-established safety profiles, as it has been marketed for over 60 years for the treatment of malaria, rheumatoid arthritis, and systemic lupus erythematosus. While most of the side effects reported are for more than one dose of hydroxychloroquine, as a healthy volunteer who is receiving a single dose of the drug, patients may or may not experience some of these common side effects: Nausea, vomiting, stomach pain or cramps, loss of appetite, weight loss, diarrhea, dizziness, spinning sensation, headaches, ringing in the ears, mood changes, nervousness, irritability, skin rash, itching, hair loss and blurred vision.

Where is the study run from?
F. Hoffmann-La Roche Ltd (USA)

When is the study starting and how long is it expected to run for?
June 2021 to May 2022

Who is funding the study?
F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?
Trial Information Support Line (TISL)
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