Summary of Clinical Trial Results

A study to find out if a standard blood collection technique used in clinical trials can be replaced with better options

See the end of the summary for the full title of the study.

About this summary

This is a summary of the results of a clinical trial (called a "study" in this document).

This summary is written for:

- Members of the public
- People who took part in the study

This summary is based on information known at the time of writing.

The study started in December 2021and finished in May 2022. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. It takes many people in several studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

- **This means that you should not make decisions based on this one summary**
- **Always speak to your doctor before making any decisions about your treatment**

Contents of the summary

1. General information about this study
2. Who took part in this study?
3. What happened during the study?
4. What were the results of the study?
5. What were the side effects?
6. How has this study helped research?
7. Are there plans for other studies?
8. Where can I find more information?

Thank you to the people who took part in this study

The people who took part have helped researchers answer important questions about techniques used to collect blood samples in studies.

Key information about this study

- This study was done to find out if newer techniques could be used for collecting blood samples in clinical trials.
- People in this study were given two "antibody" type medicines and two "small molecule" type medicines. Blood samples were collected at different times.
- The study included 40 people in one country – USA.
- Researchers compared the concentration of medicine in blood samples collected using different sampling techniques.
- The main finding was 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.

1. General information about this study

Why was this study done?

"**Low volume blood sampling**" is a technique where only a small amount of blood is collected (sampled) for testing (analysis). This manner of sampling is less of a burden on people – and less than one milliliter (mL) of blood is collected.

This study was done to find out if low volume blood sampling techniques gave results comparable to the traditional blood sampling technique – when the concentration of medicines in the samples were analyzed.

If it turned out that the sampling methods gave similar results for the four medicines in this study, then researchers could use low volume blood sampling in other studies.

What were the blood sampling techniques?

"**Venipuncture**" is the process of pricking a vein with a needle stick. This has been the method for collecting blood samples as whole blood, serum, or plasma.

Today, people have access to other tools and methods for collecting blood samples.

"TASSO OnDemand" is a tool (device) that allows people to collect blood at home. The "**TASSO-M20**"generates dried blood and **TASSO-Plus** generates about a half mL of serum or plasma samples.

"**Neoteryx Mitra**" is a device that collects small blood volumes precisely from fingertips/toes and generates dried blood.

What were the medicines being studied?

The study looked at four medicines that were previously given to healthy people in other studies – and found to be safe enough – with side effects that could be tolerated.

- **Crenezumab** is an antibody medicine that may be useful for people with certain types of Alzheimer's disease. This medicine is being tested by researchers and not approved for use in any disease in people.
- **Etrolizumab** is another antibody medicine that was studied for the treatment of Ulcerative Colitis and Crohn's disease. It was found to not be useful for those diseases. This medicine is being tested by researchers and not approved for use in any disease in people.
- **Giredestrant** is a small-molecule medicine that is being developed for the treatment of people with a type of breast cancer. This medicine is being tested by researchers and not approved for use in any disease in people.
- **Hydroxychloroquine** is a medicine for malaria and autoimmune diseases. It has been used in people for over 60 years.

What did researchers want to find out?

Researchers did this study to compare new blood sampling techniques with the traditional method – venipuncture – a needle poke in the vein carried out by a medical professional.

The main question that researchers wanted to answer was:

1. Can low volume sampling be used as an alternative method for collecting blood samples?
    a. Will the new method work for testing samples – to find out the concentration of antibody medicines present in the body?
    b. Will the new method work for testing samples – to find out the concentration of small molecule medicines present in the body?

What kind of study was this?

Phase 1 study This was a "Phase 1" study, which means that this study was done to answer some basic questions. A small number of healthy people took part. The results from this study will be helpful for designing larger studies with more people to find answers to other questions.

Parallel group study There were four groups of people in this study. A parallel group study means that all groups were treated similarly except for the different medicines given to each group.

Open label study This study was an "open label" study. That means the researchers and people who took part in the study knew which medicines the people were getting.

When and where did the study take place?

The study started in December 2021and finished in May 2022. This summary was written after the study had ended.

The study took place at one study center in the USA.

2. Who took part in this study?

Forty people took part in this study. Twenty-three (58%) were female and 17 (42%) were male. They were between 41 and 52 years of age.

People could take part in the study if they met all of the following conditions:

- Men and women between 18 and 65 years old, who signed an informed consent form.
- They met the height-to-weight ratio for this study (BMI 18 to 32 kg/m^2).
- In good health – doctors asked questions, did medical exams, and blood tests.
- Test results – negative for drug abuse.
- They agreed to maintain their normal level of physical activity and refrain from strenuous exercise.
- People on the study agreed to use birth control. Men agreed to not donate sperm and women agreed to not donate eggs – for a required period.

People could not take part in the study if they met any one of the following conditions:

- They were pregnant or breastfeeding, or they intended to become pregnant during a timeframe after taking the study medicine.
- History of health issues or current health issues not allowed in this study.
- History of allergic reactions or intolerance to food and medicines.
- History of alcohol or drug addiction.
- Recently participating in any other clinical study.
- Recently using doctor-prescribed medicines, or current use of doctor-prescribed medicines not allowed in this study.
- Recent history or current use of tobacco or nicotine-containing products.
- Recent history or current use of food or drinks that contain alcohol.
- Recent history of donating blood, or receiving blood or blood products.

3. What happened during the study?

People were examined (screened) to see if they met the conditions for joining the study. This happened from 2 days up to 35 days before the study medicine was given.

There were four treatment groups:

- Crenezumab 15 mg/kg given through the vein – intravenously (IV)
- Etrolizumab 210 mg given by an injection under the skin – subcutaneously
- Giredestrant pills taken by mouth with water
- Hydroxychloroquine pills taken by mouth with water

Ten people were assigned to each group. Everyone in one group got their medicine before the next group got theirs.

People could join more than one treatment group so long as they waited long enough for the first medicine to pass through their bodies before getting the next medicine.

People in the study had a check-in visit one day before receiving the study medicine. They were at the clinic to get their medicine – this was Day 1.

Researchers had different plans (schedules) for collecting blood samples based on which medicine each person got.

Blood samples were collected using different methods:

- Venipuncture
- TASSO-Plus administered by trained staff
- Neoteryx Mitra administered by trained staff
- TASSO-Plus that was self-administered at the clinic
- Neoteryx Mitra that was self-administered at the clinic
- TASSO-M20 administered by trained staff

Blood samples were analyzed in a lab. By comparing the concentration of medicine in each sample, researchers could see how each sampling technique compared to venipuncture.

People who got crenezumab, etrolizumab, or hydroxychloroquine stayed at the clinic for 3 days. The last follow-up visit for these 3 groups was 83 days after discharge

People who got giredestrant stayed at the clinic for 9 days. There were no follow-up visits for this group.

Throughout the study, researchers kept notes on any side effects that people in the study experienced.

4. What were the results of the study?

Question 1: Can low volume sampling be used as an alternative method for collecting blood samples?

- Will the new method work for testing samples – to find out the concentration of antibody medicines present in the body?
- Will the new method work for testing samples – to find out the concentration of small molecule medicines present in the body?

Some but not all low volume sampling methods gave the same results as venipuncture. Researchers figured out that differences in medicine concentration – with different blood collection methods – could be fixed with a mathematical calculation for each sample.

- a) For antibody medicine concentrations, results with different sampling methods could be made smaller or less significant (bridged) – using a mathematical calculation – (factoring in the baseline hematocrit).
- b) For small molecule medicine concentrations, results with different sampling methods could be bridged – using a mathematical calculation – (factoring in blood/plasma partitioning).

This section only shows the key results from this study. You can find information about all other results on the websites at the end of this summary (see Section 8).

5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that happen during the study.

- If side effects were seen in this study, and the study doctor believed the side effects to be related to the medicines or to the blood sampling device, they will be described in this summary.
- Not all of the people in any one study have all of the side effects.
- Side effects can be mild to very serious and can be different from person to person.
- It is important to be aware that if any side effects are reported here, they are from this single study. Therefore, the side effects shown here may be different from those seen in other studies, or those that appear on the medicine leaflets.
- Serious and common side effects are listed in the following sections – if they were seen in this study.

Serious side effects

A side effect is considered "serious" if it is life-threatening, needs hospital care, or causes lasting problems.

There were no serious side effects reported in this study. There were no deaths in this study. Nobody in this study withdrew from the study because of a side effect.

Most common side effects

A common side effect is not serious but could be caused by the study medicine or blood sampling procedure. During this study, nobody got a common side effect.

Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see Section 8.

6. How has this study helped research?

The information presented here is from a single study of 40 healthy people. These results helped researchers learn more about low volume blood sampling techniques and whether they can be used with different types of medicines.

Researchers found that low volume blood sampling techniques gave the same results as venipuncture. For antibody medicines and small molecule medicines, the medicine concentration results with different sampling methods could be bridged – using a different mathematical calculation for each type of medicine.

No single study can tell us everything about the risks and benefits of a medicine or medical procedure. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

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7. Are there plans for other studies?

Studies are planned for crenezumab and giredestrant. Etrolizumab is no longer studied. Hydroxychloroquine is an approved medicine that has been in use in people for over 60 years.

8. Where can I find more information?

You can find more information about this study on the websites listed below:

- https://www.isrctn.com/ISRCTN10792815
- https://forpatients.roche.com/en/trials/healthy-volunteers/a-study-to-compare-low-volume-blood-sampling-techniques-versus-c.html

Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/About.html
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

Who organized and paid for this study?

This study was organized and paid for by Genentech, Inc., South San Francisco, CA, USA. Genentech is part of F. Hoffmann-La Roche Ltd., with headquarters in Basel, Switzerland.

Full title of the study and other identifying information

The full title of this study is:

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

- The protocol number for this study is GE43429.
- The ISRCTN identifier for this study is 10792815.