Clinical Trial RESULTS

AstraZeneca

Research Sponsor: AstraZeneca

Drug Studied: Anifrolumab

National Clinical Trial #: NCT02601625

Protocol #: D3461C00006

Study Date: November 2015 to May 2016

Short Study Title: A study in healthy participants to see how anifrolumab acts in the body and how safe it is to take

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for the drug anifrolumab. This drug is being developed to treat an autoimmune disease called lupus, or lupus-related swelling in the kidneys. You and all of the participants helped researchers learn how anifrolumab acts in the body and if the drug causes medical problems.

AstraZeneca, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

What has happened since my study ended?

Your study started in November 2015 and ended in May 2016. It included 30 participants at 1 study site in the United States. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Before a new drug can be approved, research must be done to show that it is safe and effective. One of the first steps in studying a new drug is to test it in healthy people, or in people without any serious health problems.

Researchers were looking for a better way to treat lupus. Those with lupus may have higher levels of certain proteins that cause their immune system to attack healthy cells in the body. One of these proteins is called Type I interferon. The trial drug anifrolumab is a type of antibody that can block this protein. Antibodies are normally made by the body's immune system to fight off infection. Researchers are now able to use antibodies as medications to treat a variety of conditions, including lupus.

In the study, the researchers compared anifrolumab to a placebo. A placebo looks like the study drug but contains no real medicine in it. Participants got anifrolumab or the placebo in 1 of 3 ways.

They got their treatment through:

- an injection under the skin
- a needle in their vein, called an IV needle
- an infusion pump. An infusion pump has a needle like an IV needle, but it is attached to a machine that controls how much medicine a person will get through the needle.

Researchers wanted to know:

- How did anifrolumab act in the body?
- What medical problems did participants have after getting anifrolumab?

Your study included healthy men and women who were 19 to 55 years old.

What kind of study was this?

Your study was a "double-blind" study. This means that none of the participants, researchers, or staff knew what treatment each participant received. Some studies are done this way because knowing what treatment each participant is getting can affect the results of the study. This way, the results are looked at fairly.

In this study, all participants got either anifrolumab or a placebo. Participants were separated into different groups by chance, like rolling dice.

What happened during the study?

You and other participants were in the study for up to 16 weeks.

First, to see if you could join the study, researchers did a physical exam, including checking your height, weight, and temperature. They asked about your medical history, how you were feeling, and what medicines you were taking. If you are female, you had a blood or urine test to make sure you were not pregnant.

Once you joined the study, you were randomly assigned to get one of the 4 treatments listed below.

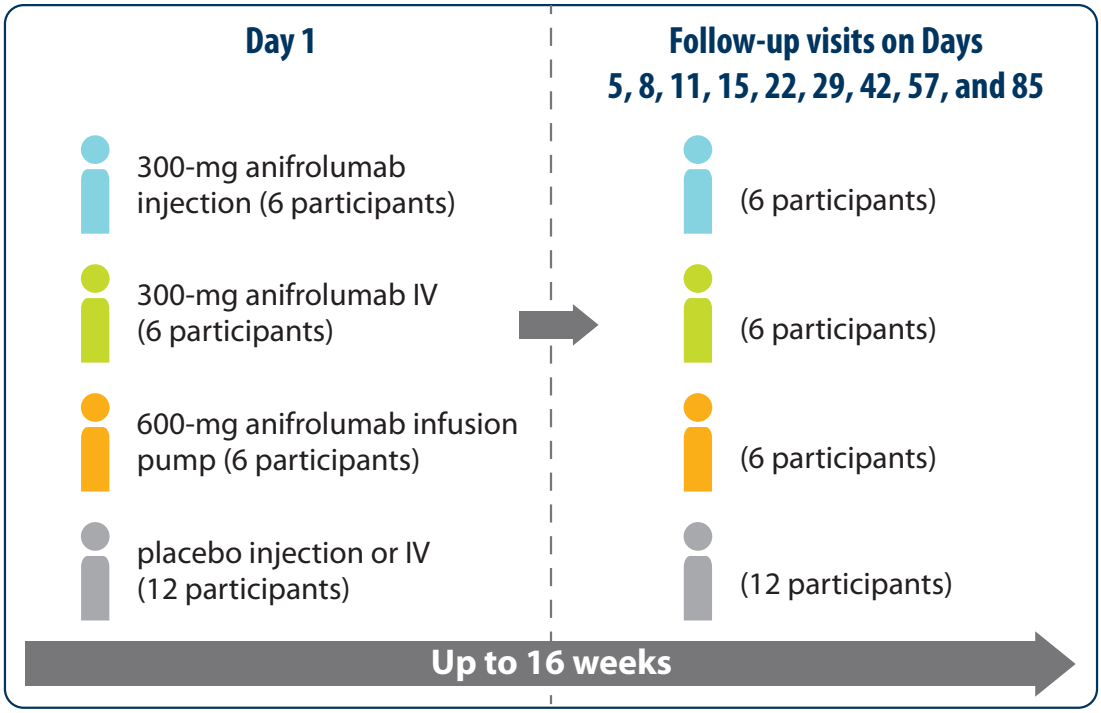
During the study, 30 participants were randomly assigned, like rolling dice, to take anifrolumab or a placebo:

- 6 participants got 300 milligrams (mg) of anifrolumab through 2 injections.
- 6 participants got 300 mg of anifrolumab through an IV needle.
- 6 participants got 600 mg of anifrolumab through an infusion pump.
- 12 participants got a placebo through an injection or IV needle.

Participants stayed at the study center for 3 days during treatment.

All participants got the treatment on Day 1 after they were at the study site for 24 hours. They got treatment on Day 1 only and left the study site after Day 3. Participants returned for follow up visits on Days 5, 8, 11, 15, 22, 29, 42, 57, and 85.

The figure below shows how the study was done.



During the study, researchers checked each participant's blood pressure, pulse rate, and temperature. They also took blood for testing, and checked the heart using an electrocardiogram, or ECG. Researchers also asked participants how they were feeling, and if they had any pain where they got the injection.

After the treatments were over, participants returned to the study center for follow-up visits 5, 8, 11, 15, 22, 29, 42, 57, and 85 days after getting anifrolumab or a placebo. During these visits, researchers continued to take blood and urine samples, and to ask participants how they were feeling. Researchers also did an ECG to check participants' heart health, and did a full physical exam at the last visit on Day 85.

What were the study results?

Below is a summary of the results of some of the questions the researchers asked during this study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for participants. Further clinical studies with anifrolumab are planned in 2017.

How did anifrolumab act in the body?

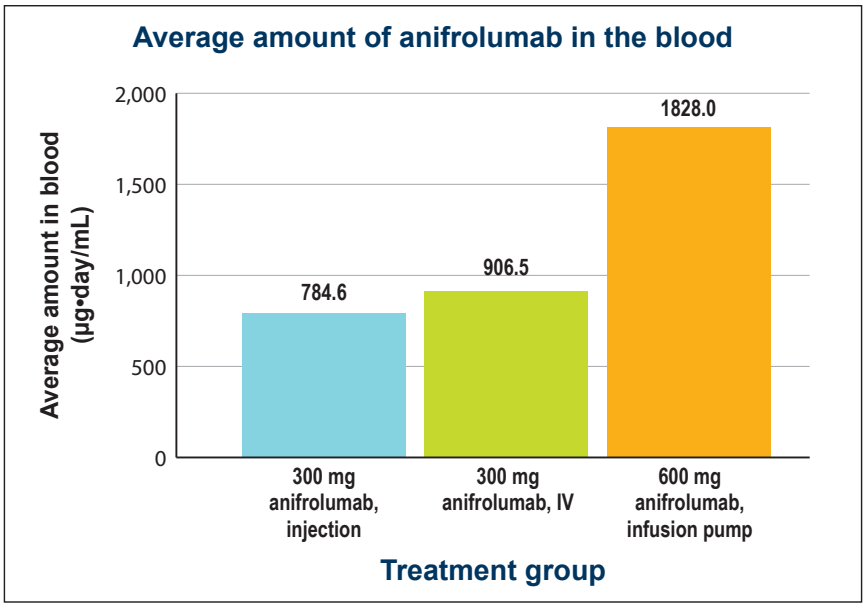
Researchers wanted to see how the study drug acted in the body. They wanted to know:

- The average amount of anifrolumab in the blood
- The highest amount of anifrolumab in the blood
- How long it took for anifrolumab to reach its highest amount in the blood

Average amount of anifrolumab in the blood

Researchers measured the average amount of anifrolumab in participants' blood in micrograms each day per milliliter of blood, or µg•day/mL. This is a widely accepted scientific unit of measurement.

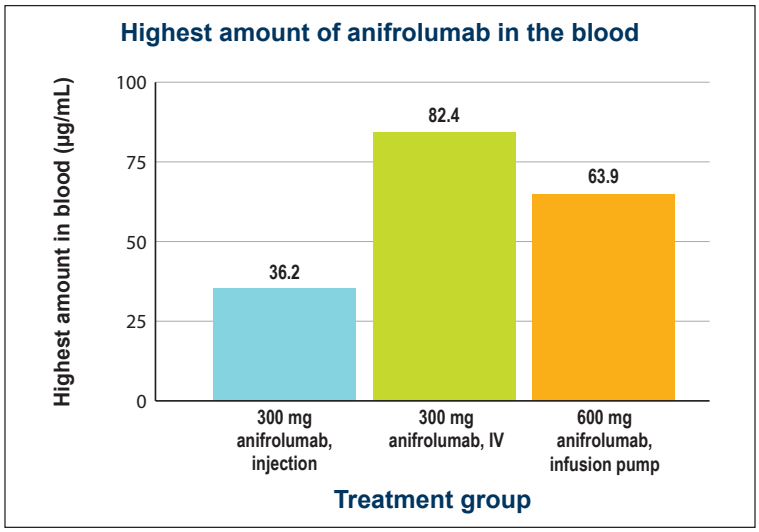
The figure below shows this amount for the 3 anifrolumab treatment groups.



Highest amount of anifrolumab in the blood

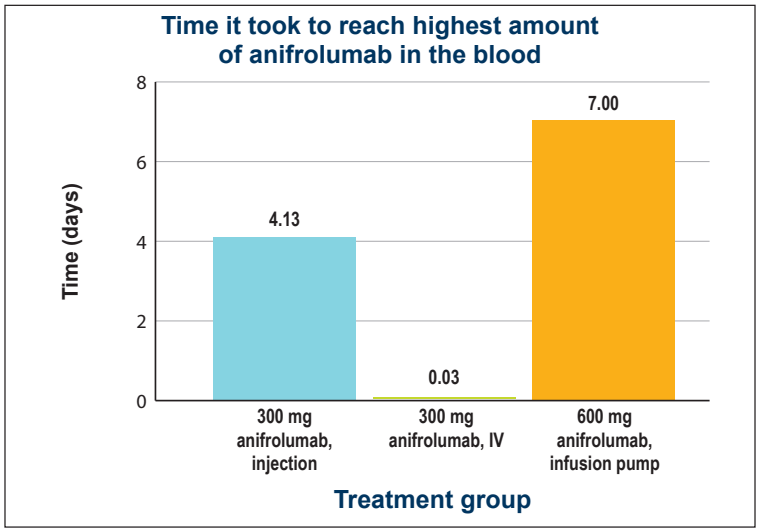
Researchers measured the highest amount of anifrolumab in participants' blood in micrograms per milliliter of blood, or µg/mL. This is a widely accepted scientific unit of measurement.

The figure below shows this amount for the 3 anifrolumab treatment groups.



Time it took for anifrolumab to reach its highest amount in the blood

Researchers measured the time in days that it took for anifrolumab to reach its highest amount in participants' blood. The figure below shows this time for the 3 anifrolumab treatment groups.



As the researchers expected, they found the following results:

- The average and highest amounts of anifrolumab in the blood were higher in participants who got a 600-mg infusion pump than in those who got a 300-mg injection.
- The average amount of anifrolumab in the blood was higher in participants who got 300 mg in an IV needle than in those who got 300 mg through an injection.

What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are studied, researchers keep track of all medical problems that participants have during the study. These medical problems are called "adverse events". They may or may not be caused by the study drug.

How many participants had medical problems in the study?

Overall, 9 out of 18 participants who got anifrolumab (50.0%) and 4 out of 12 participants who got a placebo (33.3%) had at least 1 medical problem. Twenty total medical problems were reported for participants who got anifrolumab, and 4 medical problems were reported for participants who got a placebo.

The table below shows how many participants had medical problems during the study by treatment group.

	Injection of 300 mg of anifrolumab (6 participants)	IV of 300 mg of anifrolumab (6 participants)	Infusion pump of 600 mg of anifrolumab (6 participants)	Placebo (12 participants)
How many participants developed medical problems?	3 (50.0%)	2 (33.3%)	4 (66.7%)	4 (33.3%)

How many participants developed serious medical problems?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospital care. No participants developed serious medical problems in this study, and no participants died during this study.

What were the most common non-serious medical problems in the study?

The table below shows the most common medical problems that occurred in at least 2 participants in each treatment group.

	Injection of 300 mg of anifrolumab (6 participants)	IV of 300 mg of anifrolumab (6 participants)	Infusion pump of 600 mg of anifrolumab (6 participants)	Placebo (12 participants
Common cold	2 (33.3%)	1 (16.7%)	0 (0.0%)	1 (8.3%)
Dry throat	0 (0.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)

Where can I learn more about the study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/NCT02601625

Official study title: A Study to Assess the Pharmacokinetics and Safety of Single Doses of Anifrolumab in Healthy Subjects

The phone number for the AstraZeneca Information Center is 1-877-240-9479.

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical trials, nor is it involved in conducting clinical trials.

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