Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Verinurad

Study Title: A study to find out how much verinurad gets into the blood of healthy participants using different forms

Thank you!

Thank you to the participants who took part in the clinical study for the study drug verinurad.

AstraZeneca AB sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results.

If you participated in the study and have questions about the results, please speak with the doctor or staff at your study site.

What is happening with the study now?

The study started in July 2019 and ended in September 2019. The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

This study included 25 participants in Germany.

Why was the research needed?

Researchers are looking for a better way to treat chronic kidney disease, also known as CKD. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

Verinurad is being developed as a treatment for CKD. In this study, the researchers compared 3 different forms of verinurad. They wanted to find out how different forms affected the amount of verinurad that got into the participants' blood.

The main questions the researchers wanted to answer in this study were:

- How much verinurad got into the participants' blood?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done that help find out if verinurad improves the health of people with CKD.

The researchers asked for the help of healthy men and women. Everyone in the study was aged 19 to 49 when they joined.

What kind of study was this?

This was an "open-label" study. This means the researchers and the participants knew what the participants were taking.

In this study, all of the participants took 3 different forms of verinurad. These forms were called ER8, A, and B. Each form was made in a different way, but the participants took each form as a capsule by mouth. Forms A and B were taken with food or without food and form ER8 was only taken without food. The dose of verinurad was measured in milligrams, also known as mg. Each dose was 12 mg.

There were 5 treatment periods in this study, and each treatment period lasted for 5 days. Each participant completed each treatment period. Each participant waited at least 5 days between the start of each treatment period.

A computer program was used to randomly choose the order that each participant took each treatment. This helps make sure the order is chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

The chart below shows the treatments each participant took.

Treatment 1	12 mg of ER8 form of verinurad without food
Treatment 2	12 mg of form A of verinurad without food
Treatment 3	12 mg of form A of verinurad with food
Treatment 4	12 mg of form B of verinurad without food
Treatment 5	12 mg of form B of verinurad with food

What happened during the study?

Up to 28 days before the participants took study treatment, they visited their study site once. At this visit, the doctors checked the overall health of the participants to make sure that they could join the study. The doctors:

- asked the participants about their health and about any medications they were taking
- did a physical exam
- checked the participants' blood pressure
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG

The study doctors also did these tests and measurements throughout the study.

During each treatment period, the participants stayed overnight at their study site for 5 days. They took 1 dose of verinurad in the morning on Day 2 of each treatment period.

After the participants finished taking study treatment, they visited their study site once more, up to 14 days after their last dose.

What were the results of the study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment change.

The websites listed at the end of this summary may have a full report of the study results.

How much verinurad got into the participants' blood?

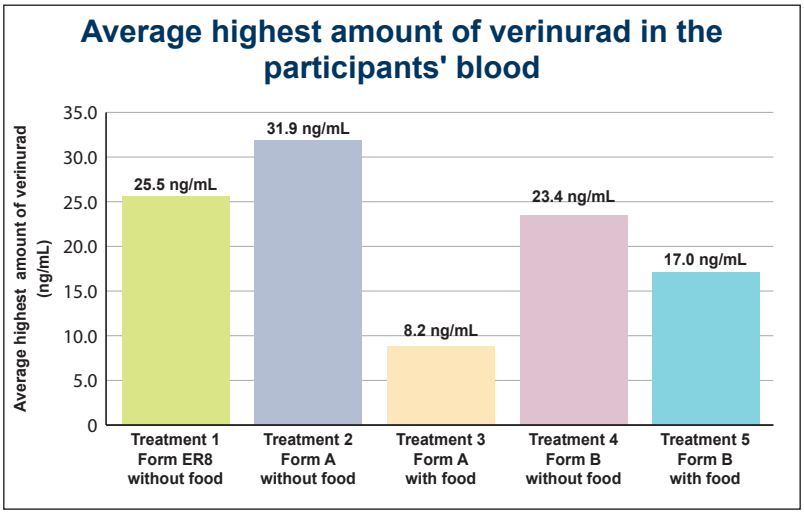
To answer this, the study doctors took blood samples from the participants during each treatment period. From the samples, they measured:

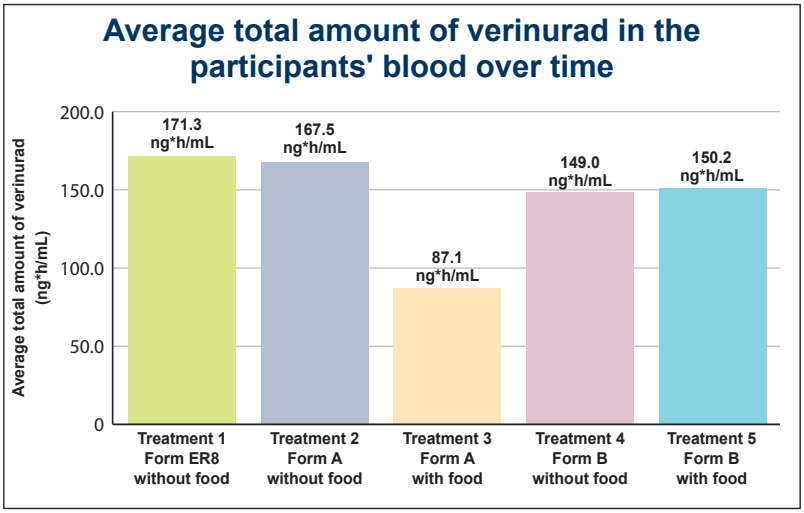
- The average highest amount of verinurad in the participants' blood. This was measured in nanograms per milliliter, also known as ng/mL.
- The average total amount of verinurad in the participants' blood over time. This was measured in nanograms per milliliter per hour, also known as ng*h/mL.
- The average total amount of verinurad in the participants' blood, up until the last blood sample taken during the study. This was also measured in ng*h/mL.

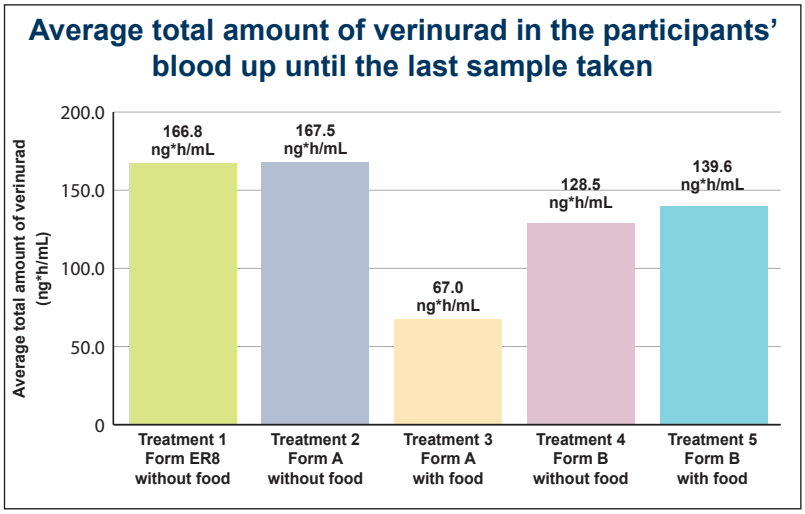
Some of the participants did not have all of the blood tests done. So, the results for each blood test below include the participants in each treatment period who had that blood test done.

For each measurement, the researchers found that the average amount of verinurad in the participants' blood was lowest when they took verinurad in Form A with food. The average amount of verinurad in the participants' blood was similar when they took the other treatments.

This is shown in the charts below.







What medical problems did participants have during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study drug. These medical problems are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions may or may not be caused by the study drug. A lot of research is needed to know whether a drug causes an adverse reaction.

The websites listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

How many participants had serious adverse reactions?

None of the participants had serious adverse reactions during this study.

How many participants had adverse reactions?

There were 16% of participants that had adverse reactions during this study. This was 4 out of 25 participants. Some participants had adverse reactions during more than 1 treatment period.

- 8% of participants had adverse reactions after taking Form ER8 without food. This was 2 out of 25 participants.
- None of the participants had adverse reactions after taking Form A without food.
- 4% of participants had adverse reactions after taking Form A with food. This was 1 out of 25 participants.
- 8% of participants had adverse reactions after taking Form B without food. This was 2 out of 25 participants.
- None of the participants had adverse reactions after taking Form B with food.

None of the participants stopped taking study treatment because of adverse reactions they had during the study.

What adverse reactions did the participants have?

The most common adverse reaction was a headache.

The table below shows the adverse reactions that happened during the study.

Adverse reactions during the study

Adverse reaction	Form ER8 without food (out of 25 participants)	Form A without food (out of 25 participants)	Form A with food (out of 25 participants)	Form B without food (out of 25 participants)	Form B with food (out of 25 participants)	Total (out of 25 participants)
Headache	4% (1)	0% (0)	4% (1)	4% (1)	0% (0)	8% (2)
Stomach pain	0% (0)	0% (0)	0% (0)	4% (1)	0% (0)	4% (1)
Diarrhea	0% (0)	0% (0)	0% (0)	4% (1)	0% (0)	4% (1)
Back pain	4% (1)	0% (0)	0% (0)	0% (0)	0% (0)	4% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about how much verinurad got into the blood of healthy participants when taken in different forms.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with verinurad are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If a full report of the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT04024501"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5495C00005"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Randomised, Single-dose, 5-period, 5-treatment, Crossover Study to Assess the Relative Bioavailability of 3 Different Extended-release Formulations of Verinurad in Healthy Subjects

National Clinical Trials Number: NCT04024501

AstraZeneca AB Protocol Number: D5495C00005

AstraZeneca AB sponsored this study and has its headquarters at 151 85 Södertälje, Sweden.

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

Thank you!

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

CISCRP

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 studies, nor is it involved in conducting clinical studies.

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