Clinical Study Results

Ardea Biosciences
A member of the AstraZeneca Group

Research Sponsor: Ardea Biosciences, Inc.

Drug Studied: Lesinurad/Allopurinol Fixed-Dose Combination

Short Study Title: A study to measure and compare healthy adults' blood levels of lesinurad and allopurinol after being taken in a combined tablet and separate tablets, both on an empty stomach

Thank you!

Thank you for taking part in the clinical study for the drugs lesinurad and allopurinol. These drugs have been developed to treat gout, a type of arthritis. You and the other participants helped researchers learn if these drugs acted the same way in the body when taken on an empty stomach in a combined tablet or in separate tablets. The study started in August 2017 and ended in October 2017.

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

Why was the research needed?

Researchers are looking for a better way to treat gout. Before a treatment can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

In this study, the researchers wanted to find out if the participants had any medical problems during the study. They also wanted to find out how lesinurad and allopurinol work in the body when they're combined into 1 tablet.

What kind of study was this?

This was an "open-label" study. This means the participants and study staff knew what study drug each participant took.

What happened during the study?

All participants were healthy men and women between the ages of 19 and 48 years.

Before participants stayed at the study site, the doctors did a physical exam and took blood and urine samples to make sure they could participate in the study.

Participants stayed at the study site up to 26 days. The doctors checked participants' blood pressure, heart rate, and body temperature. They also took more blood samples to measure the amount of lesinurad and allopurinol in the blood.

Participants took study drugs on Day 1, Day 8, Day 15, and Day 22. On each of these days, they took either Treatment A or Treatment B:

- **Treatment A:** One combined tablet of lesinurad and allopurinol taken on an empty stomach.
- **Treatment B:** One tablet of lesinurad and one tablet of allopurinol taken on an empty stomach.

All of the participants took each treatment twice. The order that the treatments were taken was different for each group. The researchers used a computer program to randomly choose the order.

Participants stayed at the study site from Day 1 until Day 26. They went back to the study site for a follow up visit around Day 29, about a week after their last dose of study drug. At this last visit, study doctors did a physical exam, took blood and urine samples, and did an ECG to check the heart health of participants. Study doctors also asked questions about any medical problems participants were having and other drugs they were taking.

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 may not be in this summary. A full list of the questions the researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

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 changes.

How did lesinurad and allopurinol act in the body?

The researchers wanted to know how lesinurad and allopurinol acted in the body when taken in one tablet compared to when they were taken in separate tablets. Researchers measured the average amounts of lesinurad and allopurinol in the blood and the highest amounts in the blood.

The researchers used microgram hours per milliliter, also called µg·hr/mL, to measure the average amounts in the blood.

The researchers found that:

- Participants had about the same amounts of lesinurad and allopurinol in their blood no matter which treatment they took.

The researchers used microgram per milliliter, also called µg/mL, to measure the highest amounts in the blood.

The researchers found that:

- Participants had about the same highest amounts of lesinurad and allopurinol in their blood no matter which treatment they took.

What medical problems did participants have after taking lesinurad and allopurinol?

The medical problems participants have during clinical studies that the doctors think might be related to the study drug are called "adverse reactions". An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study 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 adverse reactions that happened in this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. The websites listed at the end of this summary may have other information about medical problems that happened in this study.

Where can I learn more about the 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 also can be found there.

- www.clinicaltrials.gov. Once you are on the website, type **RDEA594-504** into the search box called **"Other Terms"**. Then, click **"Search"**.

If you have questions about the study results, please speak with the doctor, research nurse, or other team member at your study site.

Please also refer to the informed consent form you signed before joining this study for more details.

Official study title: A randomized, open-label, replicate, crossover, 4 period study to assess the bioequivalence of lesinurad/allopurinol fixed-dose combination 200/300 mg tablets from Ardea Biosciences, Inc. (test drug) versus lesinurad, 200 mg tablet from AstraZeneca (comparator 1) coadministered with Zyloric®, allopurinol 300 mg tablet from Aspen Pharma Industria Farmaceutica Ltda. (comparator 2) in healthy female and male adult subjects, under fasting conditions.

The protocol number of your study is: RDEA594-504

Ardea Biosciences, Inc., the sponsor of this study, is a member of the AstraZeneca Group and is located at 9390 Towne Centre Drive, San Diego, CA, 92121, United States of America.

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 participants.