Clinical Trial RESULTS

Ardea Biosciences
A member of the AstraZeneca Group

Research Sponsor:	Ardea Biosciences, Inc.
Drug Studied:	Lesinurad/Allopurinol Fixed-Dose Combination
Study Drug Indication:	Gout
National Clinical Trial #:	NCT02888054
Protocol #:	RDEA594-503
Study Date:	August 2016 to October 2016
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 with food

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 drugs lesinurad and allopurinol. These drugs have been developed to treat gout, a type of arthritis.

You and all of the other participants helped researchers learn if lesinurad and allopurinol acted the same way in the body when given with food as 1 combined tablet or 2 separate tablets.

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 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's happened since my study ended?

The study started in August 2016 and ended in October 2016. The entire study took about 2 months to complete. It included 28 participants at 1 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?

Gout is a type of arthritis, or inflammation of the joints, that can cause pain and stiffness. Even though you and the other participants in this study didn't have gout and were considered healthy, researchers believe that the results of this study will help patients who do have gout.

In healthy people, uric acid is made when your body breaks down certain substances. It usually leaves your body through urine. But gout can happen when uric acid does not leave your body properly and instead builds up in the blood and joints. The study drugs lesinurad and allopurinol are both used to treat gout by helping reduce uric acid in your body. The sponsor wanted to find out if it is effective to combine the 2 drugs into 1 tablet.

In this study, researchers wanted to know:

- Did similar amounts of lesinurad and allopurinol stay in participants' blood when taken with food as 1 combined tablet compared to separate tablets?
- Did participants have medical problems during the study?

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?

There were 28 participants in this study. All participants were healthy adults between the ages of 18 and 65 years.

Before participants stayed at the study site, study doctors did a physical exam, took blood and urine samples, and asked about participants' medical history to make sure they could participate in the study. They checked participants' blood pressure, heart rate, and body temperature. Study doctors also did an electrocardiogram, or ECG, to check participants' heart health

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

There were 4 groups in the study. Participants were assigned to groups by chance, like rolling dice.

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

- **Dose A:** One combined 200/300-milligram (mg) tablet of lesinurad/allopurinol given with food
- **Dose B:** One 200-mg tablet of lesinurad and one 300-mg tablet of allopurinol given with food

Each participant took Dose A twice and Dose B twice over those 4 days. The order that the doses were taken was different for each group. The order that each participant took the doses was decided by chance.

Participants stayed at the study site from Day 1 to 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 your health. Study doctors also asked questions about any medical problems participants were having and other drugs they were taking.

The picture below shows how the study was done.

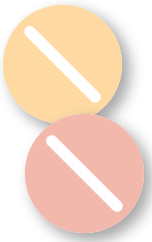
How the study was done

Who took part in this study?

- There were 28 participants in this study.
- They were all healthy adults between the ages of 18 and 65.

- All the participants visited 1 study site.

Two different doses in this study



- **Dose A:** One combined 200/300-milligram (mg) tablet of lesinurad/allopurinol given with food.
- **Dose B:** One 200-mg tablet of lesinurad and one 300-mg tablet of allopurinol given with food.
- The order that the doses were taken was different for each group.
- Each participant took Dose A twice and Dose B twice.

What were the study results?

Below is a summary of the results of some of the questions researchers asked during the study. It is important to know that researchers look at the results of many studies to decide which doses work the best and are the safest for patients. Further clinical studies with lesinurad and allopurinol are currently planned.

Did similar amounts of lesinurad and allopurinol stay in participants' blood when taken with food as 1 combined tablet compared to separate tablets?

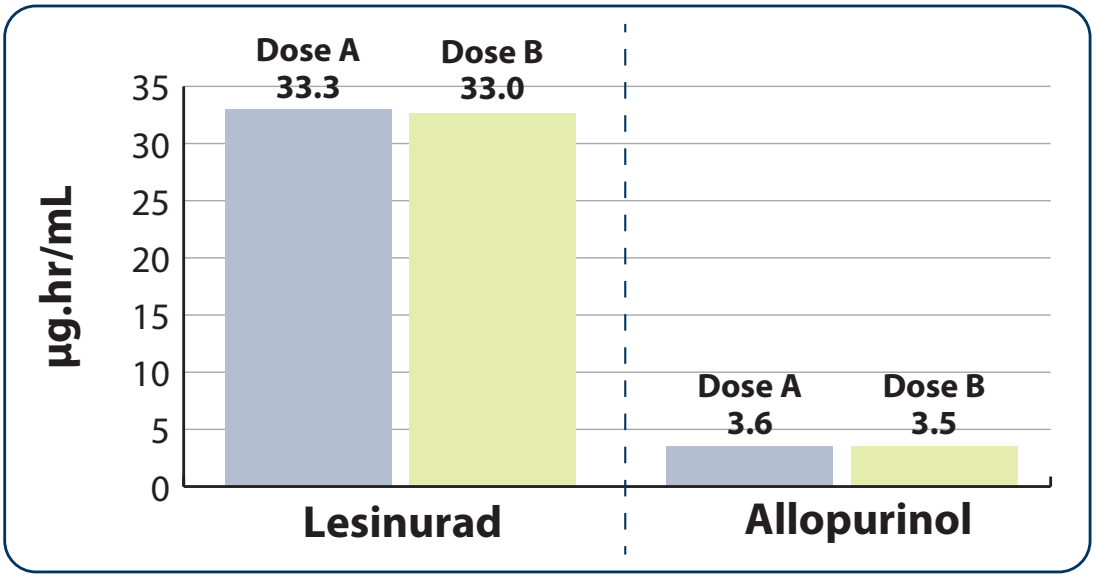
Overall, researchers found that participants had about the same amounts of lesinurad and allopurinol in their blood no matter which dose they took. The highest amount of each drug in the participants blood was also about the same no matter which dose they took.

Total amount of study drugs in participants' blood

Researchers compared the average total amounts of lesinurad and allopurinol in the blood of participants after taking the combined tablet (Dose A) to the total amounts after taking separate tablets (Dose B). Researchers measured the amounts of lesinurad and allopurinol that stayed in participants' blood over time in microgram hours per milliliter, or µg·hr/mL. This is a widely accepted scientific unit of measurement.

The picture below shows the results for Doses A and B.

Average total amount of study drugs in the blood by dose

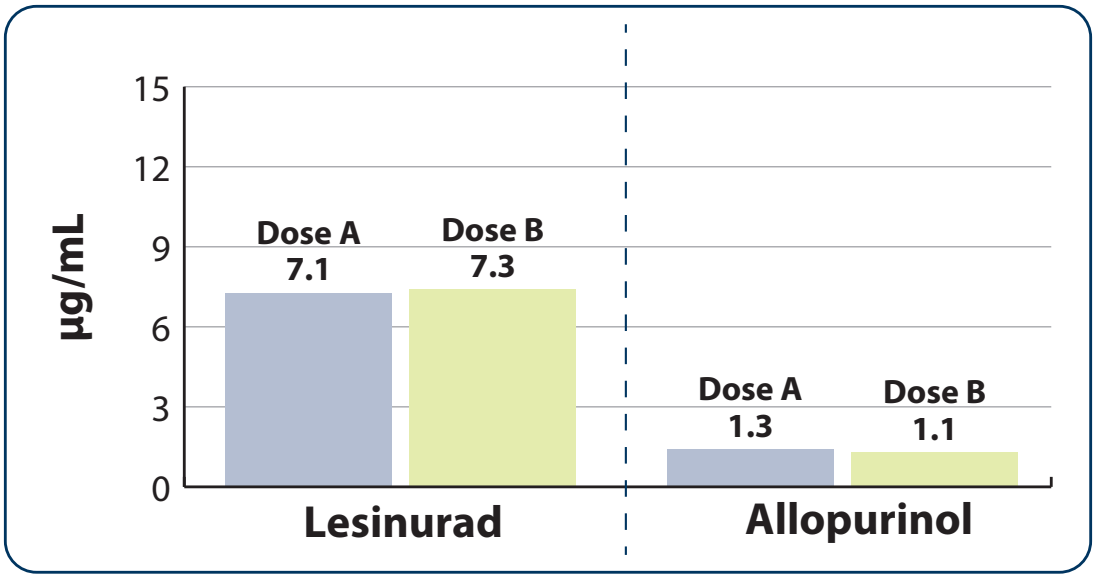


Highest level of study drugs in participants' blood

Researchers compared the average highest levels of lesinurad and allopurinol in participants' blood after they took the combined tablet (Dose A) to the average highest levels after they took separate tablets (Dose B). Researchers measured these levels in micrograms per milliliter, or µg/mL. The picture below shows the results for Doses A and B.

The picture below shows the results for Doses A and B.

Average highest levels of study drugs in the blood by dose



What medical problems did participants have during the study?

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

During this study, 5 out of the 28 participants (17.9%) had at least 1 medical problem after taking Dose A. None of the participants had medical problems after taking Dose B. None of the participants left the study because of medical problems.

The table below shows how many participants had medical problems in this study after taking Dose A and Dose B.

	Dose A (out of 28 participants)	Dose B (out of 28 participants)
How many participants had medical problems?	5 (17.9%)	0 (0.0%)
How many participants had serious medical problems?	0 (0.0%)	0 (0.0%)

What were the most common medical problems?

The only medical problems that happened in more than 1 participant after taking Dose A were:

- 2 participants (7.1%) had nausea
- 2 participants (7.1%) had pain in the arm or hand from blood tests

What serious medical problems did participants have?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospital care.

No participants had serious medical problems or died during this study.

Where can I learn more about the study?

You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02888054.

These results are from a single study, and new information or different results may happen in other studies. Changes in your medical care should not be made based on the results of a single study without speaking with your doctor or another healthcare professional. If you have questions about the results, please speak with the doctor or staff at your study site.

Official study title: A Phase 1, Randomized, Open-Label, Replicate, Crossover Study to Assess the Bioequivalence of Lesinurad/Allopurinol Fixed-Dose Combination Tablets and Coadministered Lesinurad and Allopurinol Tablets in Fed Healthy Adult Subjects.

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.

Thank you

It is said that the greatest gift is one that 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.