Clinical Trial RESULTS

Ardea Biosciences

A member of the AstraZeneca Group

Research Sponsor:	Ardea Biosciences, Inc.
Drug Studied:	RDEA3170
Study Drug Indication:	Gout
National Clinical Trial #:	NCT02608710
Protocol #:	RDEA3170-112
Study Date:	November 2015 to January 2016
Short Study Title:	A study to determine how RDEA3170 acts in the body at different doses, over time, and when taken with or without 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 medicines.

Thank you for taking part in the clinical study for the study drug RDEA3170.

RDEA3170 is a study drug being developed to treat gout.

Gout is a type of arthritis or inflammation of the joints that can cause pain and stiffness. Joints are where two bones meet, like the knee or where the big toe meets the foot. Common symptoms of gout are sudden, severe attacks of pain, redness, and tender joints.

This study started in November 2015 and ended in January 2016. You and all of the other participants in this study helped researchers learn how RDEA3170 acts in the body.

Ardea Biosciences, Inc., the sponsor of this study, thanks you 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 assistance 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 November 2015 and ended in January 2016. The entire study took about 3 months to complete and included 40 men at 1 study site. The study site was located 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 given to patients, the company developing the drug must do research studies to show that it is safe and effective. The first step in studying a new drug is to test it in people without any serious health problems. This study included 40 healthy men between the ages of 18 and 65 years.

The study drug, RDEA3170, may help treat gout by helping the kidneys process a substance called uric acid. Uric acid is made when the body breaks down a substance in the body called purine. Purine is also found in some foods. Most uric acid leaves the body through urine. Gout can be caused by uric acid not leaving the body properly and instead, building up in the blood and joints.

In this study, researchers wanted know:

- Did RDEA3170 help the body get rid of uric acid?
- How much RDEA3170 was in participants' blood after each dose?
- How did RDEA3170 act in the body when taken with and without food?
- Did participants have medical problems during the study?

What kind of study was this?

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

What happened during the study?

Participants stayed at the clinical research unit for up to 14 days. Before starting this study, study doctors did a physical examination, checked participants' blood pressure, heart rate, and body temperature, took blood and urine samples, ran tests, and asked about each man's medical history to make sure they could participate in the study.

During the study, study doctors continued to check participants' blood pressure, heart rate, and body temperature. Doctors also took blood and urine samples to measure the amount of RDEA3170 and uric acid in participants' blood. They asked participants how they were feeling and did an electrocardiogram or ECG. An ECG is a test to check the heart's rhythm. At different times of the study, all participants had to fast before taking RDEA3170. Fasting means that participants cannot eat or drink for a specific time. In this study, participants could not eat or drink anything for at least 10 hours before they took RDEA3170 and for 4 hours after taking RDEA3170.

This study had 3 parts:

Part 1 had 16 participants who stayed in the clinical research unit for 14 days. Participants took a single 4.5, 6, or 12 milligram (mg) dose of RDEA3170. Each participant took all 3 doses of RDEA3170 but in a different order. They took the first dose of RDEA3170 on Day 1, another dose on Day 5, and the last dose on Day 9.

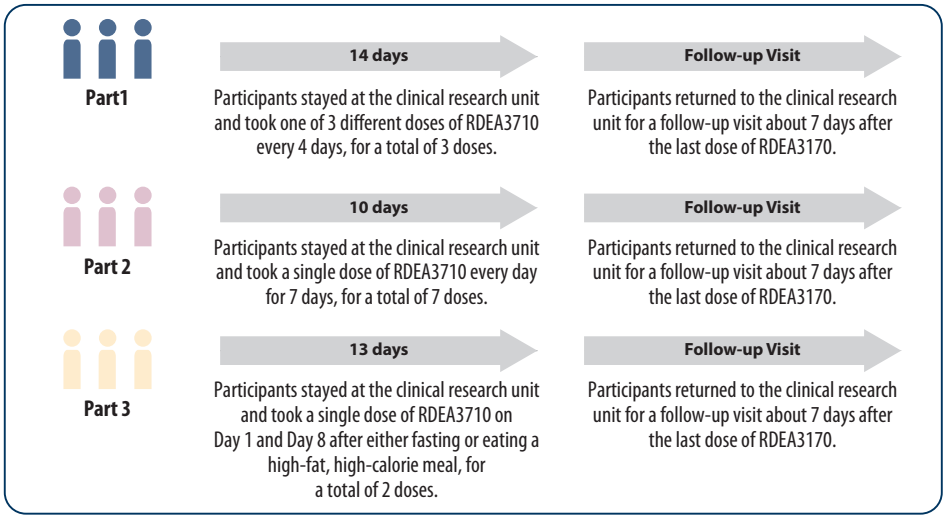
Part 2 had 8 participants who stayed in the clinical research unit for 10 days. Each participant took one 12 mg dose of RDEA3170 every day for 7 days.

Part 3 had 16 participants who stayed in the clinical research unit for 13 days. Each participant took one 6 mg dose of RDEA3170 on Days 1 and 8. On Day 1, half of the participants were assigned to take the 6 mg dose of RDEA3170 after fasting overnight and the other half of the participants were assigned to take the 6 mg dose of RDEA3170 after a high-fat, high-calorie meal. On Day 8, they switched dosing regimen.

The Follow-Up Visit

All 40 participants came back to the clinical research unit about 7 days after the last dose of RDEA3170 for a follow-up visit. Study doctors did a physical examination, checked participants' blood pressure, heart rate, and body temperature, took blood and urine samples, and answered questions about any medical problems and other drugs the participants were taking. The chart below shows the 3 parts of the study.

Three parts of this study



What were the study results?

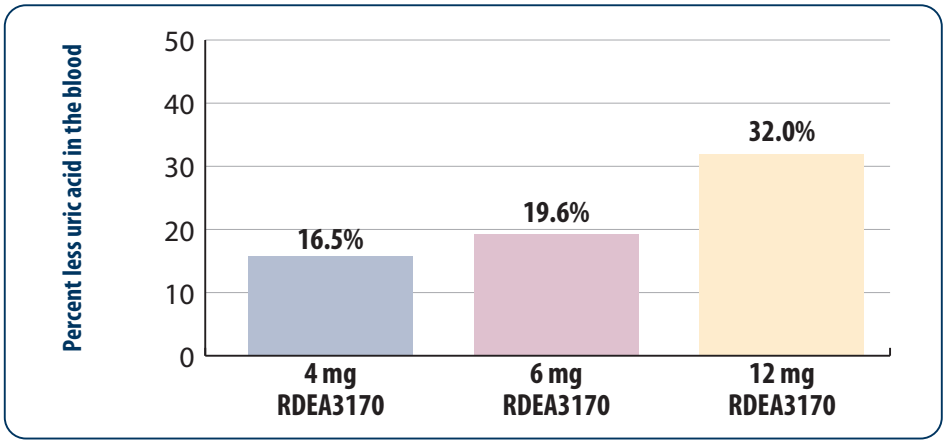
A summary of the results is presented below. These results answered some of the questions that researchers asked during the study.

Did RDEA3170 help the body get rid of uric acid?

Yes. In Part 1 of the study, participants had less uric acid in the blood 24 hours after taking RDEA3170. The higher doses of RDEA3170 resulted in less uric acid in the blood than the lower doses of RDEA3170.

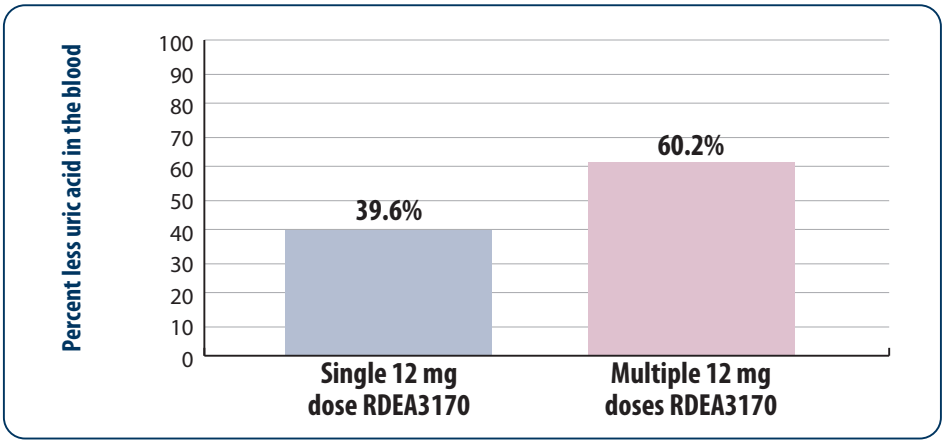
The figure below shows how much less uric acid was in the blood 24 hours after taking single doses of 4.5, 6, and 12 mg RDEA3170.

Percent less uric acid in the blood 24 hours after taking single doses of 4.5, 6, and 12 mg RDEA3170



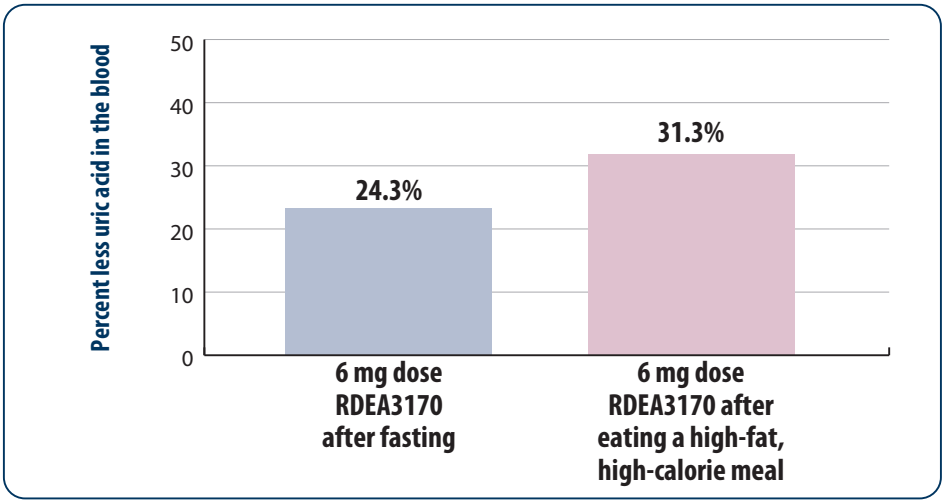
In Part 2 of the study, participants had less uric acid in the blood 24 hours after taking both single and multiple 12 mg doses of RDEA3170. Multiple 12 mg doses of RDEA3170 helped to reduce uric acid in the blood more than a single 12 mg dose of RDEA3170. The figure below shows how much less uric acid was in the blood 24 hours after taking both single and multiple 12 mg doses of RDEA3170.

Percent less uric acid in the blood 24 hours after taking single and multiple 12 mg doses of RDEA3170



In Part 3 of the study, participants had less uric acid in the blood 24 hours after taking a 6 mg dose of RDEA3170 after fasting. They also had less uric acid in the blood 24 hours after taking a 6 mg dose of RDEA3170 and eating a high-fat, high-calorie meal. Taking a 6 mg dose of RDEA3170 after eating a high-fat, high-calorie meal helped to reduce uric acid in the blood more than taking a 6 mg dose of RDEA3170 after fasting. The figure below shows how much less uric acid was in the blood 24 hours after taking a 6 mg dose of RDEA3170 after fasting and after eating a high-fat, high-calorie meal.

Percent less uric acid in the blood 24 hours after taking single doses of 6 mg RDEA3170 after fasting and after eating a high-fat, high-calorie meal



How much RDEA3170 was in participants' blood after each dose?

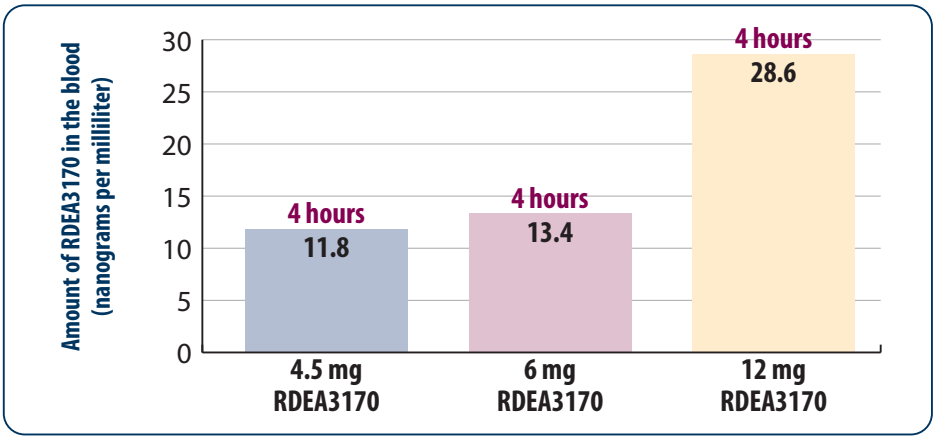
In Part 1 and 2 of the study, researchers measured the highest amount of RDEA3170 in participants' blood in nanograms per milliliter. The highest amount of RDEA3170 in participants' blood depended on which dose they took.

Researchers also measured the amount of time it took for RDEA3170 to reach the highest amount in participants' blood. The median time is the amount of time halfway between the shortest time and the longest time it took for RDEA3170 to reach the highest amount in the blood. The median time for RDEA3170 to reach the highest amount in participants' blood was 4 hours after single doses of 4.5, 6, and 12 mg RDEA3170.

In Part 1 of the study, researchers took blood samples on Days 1, 5, and 9 about 30 minutes before participants took RDEA3170. Then, more blood samples were taken every few hours each day until they were discharged from the clinical research unit.

The figure below shows the median time RDEA3170 took to reach the highest amount in the blood and the highest amount of RDEA3170 in participants' blood after single doses of 4.5, 6, and 12 mg RDEA3170.

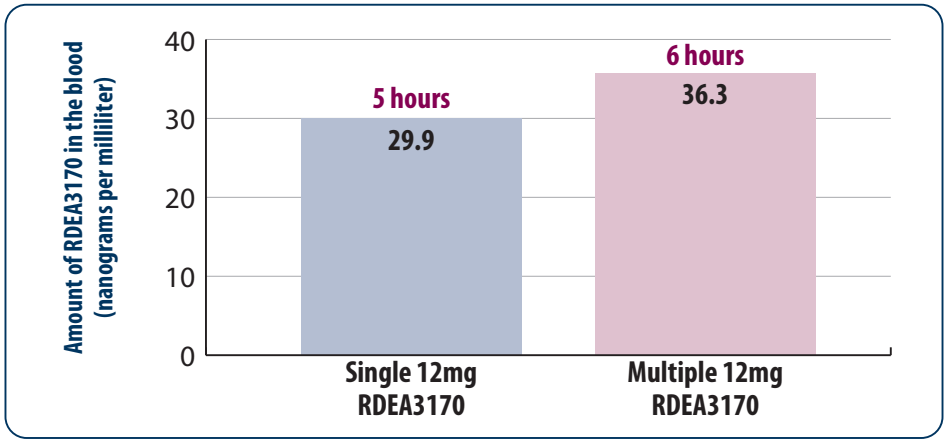
Highest amount of RDEA3170 in the blood and median time to reach the highest amount in the blood after single doses of 4.5, 6, and 12 mg RDEA3170



In Part 2 of the study, researchers took blood samples on Days 1 and 7 about 30 minutes before participants took RDEA3170. Then, more blood samples were taken every few hours for 1 day after the participants took RDEA3170.

The figure below shows the median time RDEA3170 took to reach the highest amount in the blood and the highest amount of RDEA3170 in participants' blood after a single 12 mg dose of RDEA3170 and after multiple 12 mg doses of RDEA3170.

Highest amount of RDEA3170 in the blood and median time to reach the highest amount in the blood after taking a single 12mg dose of RDEA3170 and multiple 12 mg doses of RDEA3170

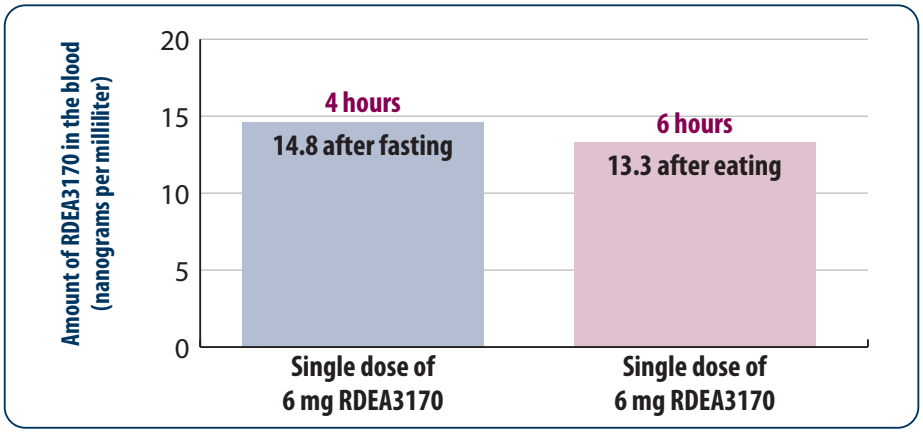


How did RDEA3170 act in the body when taken with and without food?

In Part 3 of the study, researchers took blood samples on Days 1 and 8 about 30 minutes before participants took RDEA3170. Then, researchers took more blood samples every few hours for 3 days. Researchers compared what happened when participants took the same 6 mg dose of RDEA3170 with and without food. The amount of RDEA3170 in participants' blood was the same in both groups, but it took longer for RDEA3170 to reach the highest amount after eating a high-fat, high-calorie meal.

The figure below shows the median time RDEA3170 took to reach the highest amount in the blood and the highest amount of RDEA3170 in participants' blood after fasting and after eating a high-fat, high-calorie meal.

Highest amount of RDEA3170 in the blood and median time to reach the highest amount in the blood after taking single doses of 6 mg RDEA3170 after fasting and after eating a high-fat, high-calorie meal



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 RDEA3170..

Six (15%) out of 40 participants had at least 1 adverse event during the study:

- Two (13%) out of 16 participants in Part 1 had adverse events during the study.
- Two (25%) out of 8 participants in Part 2 had adverse events during the study.
- Two (13%) out of 16 participants in Part 3 had adverse events during the study.

What serious adverse events did participants have?

An adverse event is considered serious when it is life-threatening, causes lasting problems, when a participant dies, or when a participant needs hospital care.

During this study, no participants had serious adverse events and no participants died.

What were the most common adverse events?

The table below shows the most common adverse events that happened during this study.

Most common adverse events in the study	Part 1 (out of 16 participants)	Part 2 (out of 8 participants)	Part 3 (out of 16 participants)
Diarrhea	1 participant (6%)	1 participant (13%)	0 participants (0%)
Abnormal movement of GI tract	1 participant (6%)	0 participants (0%)	0 participants (0%)
Headache	0 participants (0%)	0 participants (0%)	1 participant (6%)
Sleepiness	0 participants (0%)	0 participants (0%)	1 participant (6%)
Feeling cold	0 participants (0%)	1 participant (13%)	0 participants (0%)
Rash	0 participants (0%)	1 participant (13%)	0 participants (0%)

It is important to know that researchers look at the results of many studies to decide which study drugs work best and are safest for patients. Further clinical studies with RDEA3170 are not currently planned.

Where can I learn more about the study?

You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02608710.

Official study title: A Phase 1, Randomized, Open-Label Study in Healthy Adult Male Subjects to Assess the Pharmacokinetics and Pharmacodynamics of RDEA3170 Capsules

Ardea Biosciences, Inc., the sponsor of this study, is a Member of the AstraZeneca group of companies and has its headquarters at 9390 Towne Centre Drive, San Diego, CA 92121, US.

The phone number for the AstraZeneca Information Centre is 1-858-625-0760.

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

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 study. 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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