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 #: NCT02448368
Protocol #: RDEA3170-111
Study Date: May 2015 to June 2015
Short Study Title: A study to determine if the amount of RDEA3170 in the body is the same if taken as a capsule or a tablet and 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 medical treatments.

Thank you for taking part in the clinical study for the study drug RDEA3170. RDEA3170 is a new drug being developed to treat gout. Gout is a type of arthritis. Arthritis is an inflammation of the joints that causes pain and stiffness. Joints are where two bones meet, like the knee. Common symptoms of gout are sudden, severe attacks of pain, redness, and tenderness in joints. This study started in May 2015 and ended in June 2015. You and all of the 35 participants helped researchers learn how RDEA3170 acts in the body.

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 and a medical writing organization called Synchrogenix prepared this summary of the study results for you. 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 May 2015 and ended in June 2015. The entire study took less than 1 month to complete. It included 35 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?

Before a new medicine can be given to patients, the company developing it must do research studies to show that it is safe and effective. The first step in studying a new medicine is to test it in healthy people, before testing it in patients with the disease the medicine will treat. This can include testing different forms of the medicine, like a tablet and a capsule. A tablet is a solid pill, while a capsule is a small gelatin container. Tablets and capsules are both swallowed and both contain 1 dose of the drug.

This study had 35 healthy men between the ages of 18 and 65 years. It tested a drug called RDEA3170 that is being developed to help treat gout. Gout happens in some people who have too much uric acid in their blood. Uric acid is made when the body breaks down a substance in the body called purine. Purine is also in some foods. Most uric acid leaves the body through urine. RDEA3170 may help treat gout by helping the body get rid of more uric acid.

Until now, participants in studies took RDEA3170 as a tablet. Researchers wanted to find out if a capsule could work as well as a tablet.

Researchers wanted to know:

- Did RDEA3170 capsules give participants as much medicine as RDEA3170 tablets?
- Did eating food affect how RDEA3170 capsules act in the body?
- Did RDEA3170 help the body get rid of uric acid?
- 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.

All participants in each of the 2 groups took the same amount of the study drug in tablets and capsules, but in a different order. The order of the study drugs was assigned to each participant by chance, like the tossing of a coin.

WHAT HAPPENED DURING THE STUDY?

Participants stayed at 1 clinical research unit in the US for up to 22 days. Before starting this study, study doctors asked about each man's medical history, did a physical exam and other tests, and took blood and urine samples to make sure each man could participate.

During the study, study doctors checked participants' blood pressure, heart rate, and temperature; took blood and urine samples; and asked questions about how they were feeling. Blood samples were collected to measure the amount of RDEA3170 and uric acid in the blood.

2 Study Groups

Study doctors put participants into 1 of 2 groups. Before some doses, participants had to fast overnight. This meant they could not eat or drink anything for 10 hours before taking the study drug.

Group 1: 20 participants in Group 1 stayed in the clinical research unit for 22 days. Each participant took 1 dose of RDEA3170 every 5 days, for a total of 5 doses.

Four of the doses of RDEA3170 were capsules:

- 5 mg after fasting overnight
- 5 mg after a high-fat, high-calorie meal
- 10 mg after fasting overnight
- 10 mg after a high-fat, high-calorie meal

The fifth dose was 10 mg of RDEA3170 in 4 tablets of 2.5 mg after fasting overnight.

Group 2: 15 participants in Group 2 stayed in the clinical research unit for 14 days. Each participant took 1 dose of RDEA3170 every 5 days, for a total of 3 doses.

Two of the doses of RDEA3170 were capsules:

- 10 mg after fasting overnight
- 10 mg after a high-fat, high-calorie meal

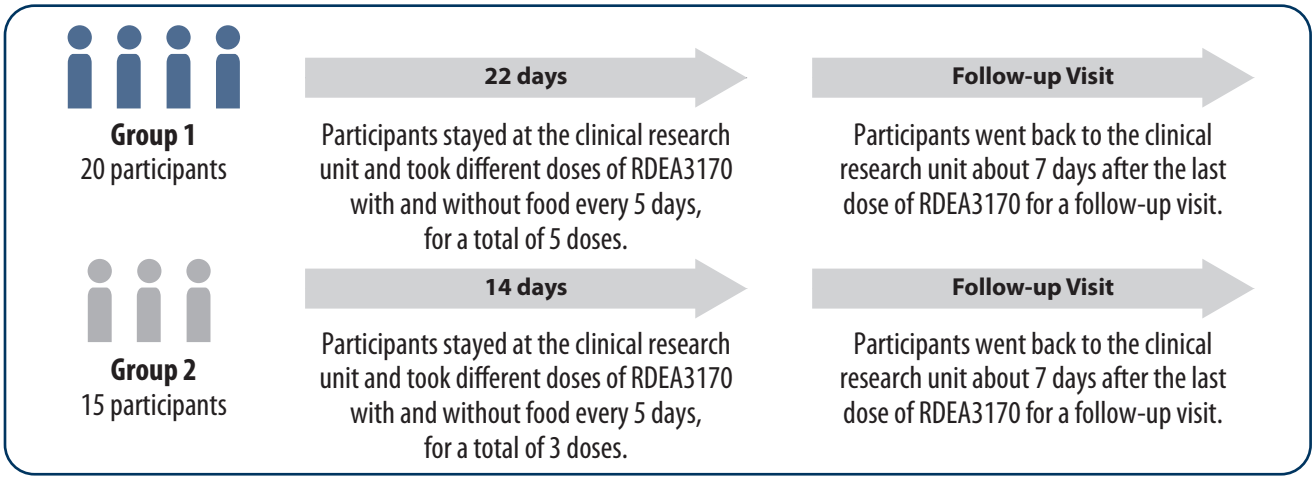
The third dose was 10 mg of RDEA3170 in 4 tablets of 2.5 mg after fasting overnight.

The Follow-Up Visit

All participants came back to the clinical research unit about 1 week after the last dose of RDEA3170 for a follow-up visit. Study doctors did a physical exam, took blood and urine samples, and answered questions about any medical problems and other drugs the participants were taking.

The chart below shows the 2 groups.

Two Groups in This Study



WHAT WERE THE STUDY RESULTS?

Below is a summary of the results of some of the questions researchers asked during the study.

Did RDEA3170 capsules give participants as much medicine as RDEA3170 tablets?

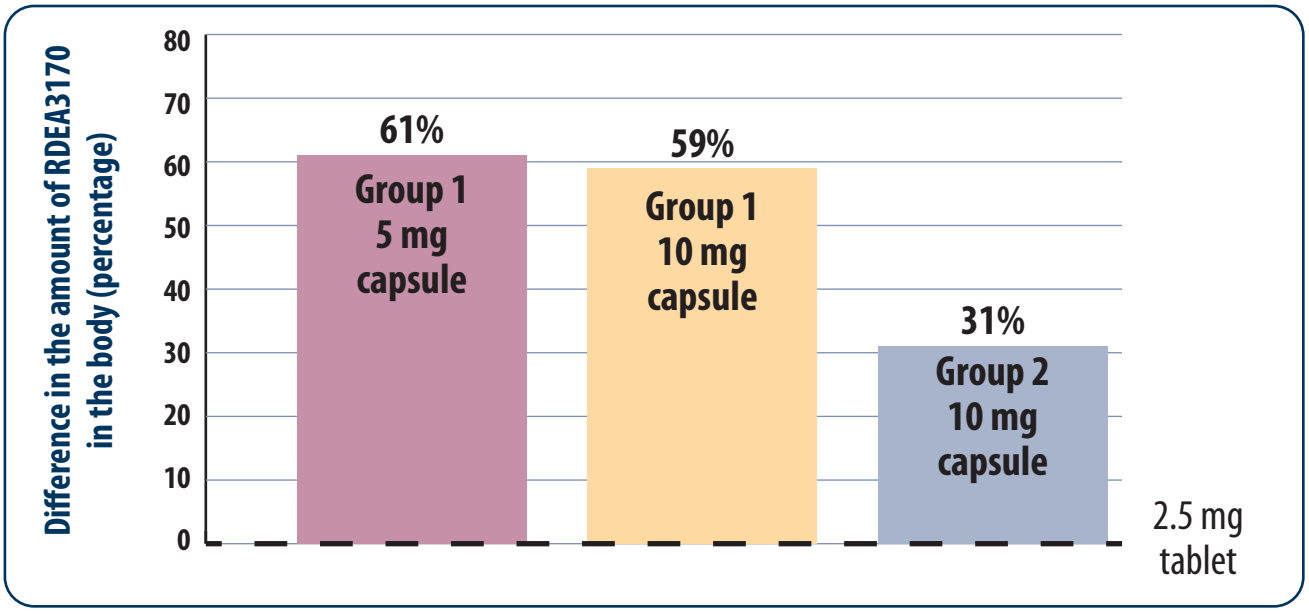
Yes. The amount of RDEA3170 in the body was higher for all 3 types of capsules compared to RDEA3170 tablets.

In Group 1, participants had about 61% more RDEA3170 in the body after taking the 5 mg capsules and about 59% more RDEA3170 in the body after taking the 10 mg capsules compared to the tablets.

In Group 2, participants had about 31% more RDEA3170 in the body after taking the 10 mg capsules compared to the tablets.

The chart below shows the difference in the amount of RDEA3170 in the body for the 3 types of capsules compared to 4 tablets totaling 10 mg.

Difference in the amount of RDEA3170 in the body compared to RDEA3170 tablets



Did food affect how RDEA3170 capsules act in the body?

There was no difference in the amount of RDEA3170 in the body when participants in Group 1 took the 5 and 10 mg capsules after eating a high-fat, high-calorie meal compared to when they took them after fasting.

When participants in Group 2 ate a high-calorie, high-fat meal and then took the 10 mg capsules, they had about 16% more RDEA3170 in their bodies than when they took them after fasting.

Did RDEA3170 help the body get rid of uric acid?

Yes. Participants in both groups had less uric acid in the blood after taking RDEA3170 capsules than after taking RDEA3170 tablets. Participants who took RDEA3170 capsules had between 29% and 52% less uric acid in their blood after taking RDEA3170 than before taking it. The amount of uric acid decreased most in participants in Group 1 after taking the 10 mg capsules after a high-calorie, high-fat meal and least in participants in Group 1 after taking the 5 mg capsules after fasting overnight.

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.

Five participants (30%) had at least 1 medical problem during the study:

Two participants in Group 1 (10%) had medical problems during the study.

- 1 participant had a virus after taking the 5 mg capsule after fasting overnight.
- 1 participant had a headache after taking the 5 mg capsule after eating a high-fat, high-calorie meal.

Three participants in Group 2 (20%) had medical problems during the study.

- 2 participants had diarrhea after taking the 10 mg capsule after fasting overnight. One of them also had diarrhea after taking the 10 mg capsule after eating a high-fat, high-calorie meal.
- 1 participant had muscle and joint stiffness after taking the 10 mg capsule after eating a high-fat, high-calorie meal.

What serious medical problems did participants have?

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

During this study, no participants had serious medical problems, and no participants died.

What were the most common medical problems?

The table below shows the most common medical problems that happened during this study.

Most common medical problems in the study	Group 1 (out of 20 participants)	Group 2 (out of 15 participants)
Diarrhea	0 participants (0%)	2 participants (13%)
Muscle and joint stiffness	0 participants (0%)	1 participant (7%)
Virus	1 participant (5%)	0 participants (0%)
Headache	1 participant (5%)	0 participants (0%)

It is important to know that researchers look at the results of many studies to decide which medicines 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/NCT02448368.

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, Study in Healthy Adult Male Subjects to Assess the Relative Bioavailability and Food Effect of Various Formulations of RDEA3170.

Ardea Biosciences, Inc., the sponsor of this study, is a member of the AstraZeneca group of companies and has its headquarters at 1800 Concord Pike, PO Box 15437, Wilmington, DE 19850. The phone number for general information is 1-877-240-9479.

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.

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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