AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Acalabrutinib

Study Purpose: This study was done to learn how acalabrutinib works and about its safety in healthy participants

Protocol Number: D8223C00013

Thank you!

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

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

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

Who took part in this study?

The researchers asked for the help of healthy men and women. The participants in this study were 18 to 56 years old when they joined.

None of the participants smoked or used any products containing nicotine for 3 months before joining the study.

The study included 66 participants in the United States.

Why was the research needed?

Researchers are looking for a better way to treat B-cell lymphoid cancer, also known as B-cell lymphoma. Before a drug or a form of a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

B-cell lymphoma is a type of blood cancer that affects B lymphocytes, which are a type of white blood cell in the immune system. The study drug, acalabrutinib, is used to treat certain types of blood cancers. It works by stopping the cancer cells from growing out of control.

Acalabrutinib in a capsule form was already studied and approved in healthy participants and participants with liver problems. Researchers are now studying acalabrutinib in a tablet form to see if it works in a similar way to the approved capsule form.

In this study, the researchers wanted to learn more about how much acalabrutinib got into the participants' blood when it was taken as a tablet, compared with when it was taken as a capsule.

What was the purpose of this study?

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

- Did the amount of acalabrutinib that got into the participants' blood differ when it was taken as a tablet compared with a capsule?
- 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 to find out if using acalabrutinib as a tablet helps improve the health of people with B-cell lymphoid cancer.

What treatments did the participants get?

In this study, all of the participants took:

- acalabrutinib as a **tablet** by mouth
- acalabrutinib as a **capsule** by mouth

The participants were split into 2 groups. Each group of participants took the 2 study treatments in a different order.

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

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

The chart below shows the treatments the researchers studied.

	Group 1 35 participants	**Group 2** 31 participants
	• Acalabrutinib as a **tablet** **THEN** • Acalabrutinib as a **capsule**	• Acalabrutinib as a **capsule** **THEN** • Acalabrutinib as a **tablet**
	• Each study treatment once after not eating • At least 5 days between each study treatment	• Each study treatment once after not eating • At least 5 days between each study treatment

What happened during this study?

The study started in February 2021 and ended in May 2021.

Before the participants took study treatment, they visited their study site once. This part of the study lasted for up to 1 month. At this visit, the study doctors made sure the participants could join the study. They also:

- did physical exams and asked about the participants' medications and any medical problems they were having
- checked the participants' smoking history
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG

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

While the participants took study treatment, they stayed at their study site. The participants took their first study treatment on Day 3. They waited at least 5 days before taking their second study treatment.

After the participants took study treatment, they visited their study site or had a phone call with the study doctor. This happened 7 to 10 days after they took their second study treatment. During this visit or phone call, the study doctors checked the health of the participants.

What were the results of this 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 changes.

The websites listed at the end of this summary may have more information about the study results.

The results below are for participants from both Group 1 and Group 2, who took the 2 study treatments in a different order. There were 4 out of 66 participants who did not take both study treatments. So, the results below are for:

- 65 participants who took acalabrutinib as a tablet
- 63 participants who took acalabrutinib as a capsule

Did the amount of acalabrutinib that got into the participants' blood differ when it was taken as a tablet compared with a capsule?

No. Overall, the researchers found that taking acalabrutinib as a tablet did not affect the amount of acalabrutinib that got into the participants' blood compared with when it was taken as a capsule.

To answer this question, the study doctors took blood samples from the participants throughout the study.

In these samples, the study doctors measured:

- the average total amount of acalabrutinib in the participants' blood during the study
- the average highest amount of acalabrutinib in the participants' blood during the study

Then, the researchers compared the results after the participants took acalabrutinib as a tablet with the results after they took it as a capsule. Overall, the researchers found that there were some small differences between the groups. But, these differences were too small for the researchers to know if taking acalabrutinib in 2 different ways affected how much of it got into the blood.

What medical problems happened during this 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for acalabrutinib.

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.

The results below are for participants from both Group 1 and Group 2, who took the 2 study treatments in a different order. There were 4 out of 66 participants who did not take both study treatments. So, the results below are for:

- 65 participants who took acalabrutinib as a tablet
- 63 participants who took acalabrutinib as a capsule

Did any adverse reactions happen during this study?

	Acalabrutinib tablet (out of 65 participants)	**Acalabrutinib capsule** (out of 63 participants)
How many participants had adverse reactions?	7.7% (5)	1.6% (1)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)
How many participants stopped taking study treatment due to adverse reactions?	0.0% (0)	0.0% (0)

What serious adverse reactions happened during this study?

No serious adverse reactions happened during this study.

What adverse reactions happened during this study?

The most common adverse reaction was a headache.

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

Adverse Reactions		
Adverse reaction	**Acalabrutinib tablet** (out of 65 participants)	**Acalabrutinib capsule** (out of 63 participants)
Headache	6.2% (4)	0.0% (0)
Sluggishness	0.0% (0)	1.6% (1)
Diarrhea	1.5% (1)	0.0% (0)
Dizziness	1.5% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about how acalabrutinib acts in the blood in healthy participants when taken in different ways.

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 acalabrutinib are planned.

Where can I learn more about this study?

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

- www.clinicaltrials.gov. Once you are on the website, type **"NCT04768985"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D8223C00013"** into the search box, and click **"Find a Study"**.

Full Study Title: Phase I, Open-Label, Randomized, 2-Treatment, 2-Period, Crossover Study in Healthy Subjects to Assess the Bioequivalence of Acalabrutinib Tablet and Acalabrutinib Capsule

AstraZeneca Protocol Number: D8223C00013

National Clinical Trials number: NCT04768985

AstraZeneca AB sponsored this study and has its headquarters at 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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