Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Savolitinib

Study Title: A study to learn how savolitinib acts in the bodies of healthy men when taken with and without famotidine

Thank you!

Thank you to the participants who took part in the clinical study for the study drug savolitinib. AstraZeneca AB sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results.

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 the study?

The researchers asked for the help of healthy men. The participants in this study were 23 to 55 years old when they joined.

The study included 16 participants in the United States.

Why was the research needed?

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

Cancer is a disease that happens when the body cannot control the growth of cells. The extra cells can form tumors, which can start in any part of the body.

The study drug, savolitinib, is being developed as a treatment for tumors. In this study, the researchers wanted to learn how savolitinib acts in the body when taken with a drug called famotidine.

Famotidine is a drug prescribed by doctors to treat certain conditions, such as high levels of acid in the stomach. The level of acid in the stomach can sometimes affect how quickly a drug gets into the blood and how much of a drug gets into the blood. So, in this study, the researchers wanted to learn how quickly savolitinib got into the blood and how much of it got into the blood when taken with and without famotidine. They also wanted to find out if the participants had any medical problems during the study.

What was the purpose of this study?

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

- How did savolitinib act in the body when taken with famotidine?
- What medical problems happened during the study?

The answers to these questions are important to know. Other studies are being done to find out if savolitinib helps improve the health of people who have tumors.

What treatments did the participants take?

The participants in this study took 2 treatments:

- savolitinib
- savolitinib and famotidine

All of the participants took both treatments, but in a different order.

The participants took both of the treatments as pills by mouth.

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

A computer program was used to randomly choose the order in which the participants took the treatments. 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.

What happened during the study?

The study started in December 2019 and ended in March 2020. The researchers planned for the study to have 2 parts. The researchers determined that famotidine did not affect how savolitinib acted in the body during the first part, so they decided not to do the second part.

Before the participants took treatment, they visited their study site 1 time over the course of about 1 month. During this visit, the study doctors checked to make sure the participants could join the study. The study doctors:

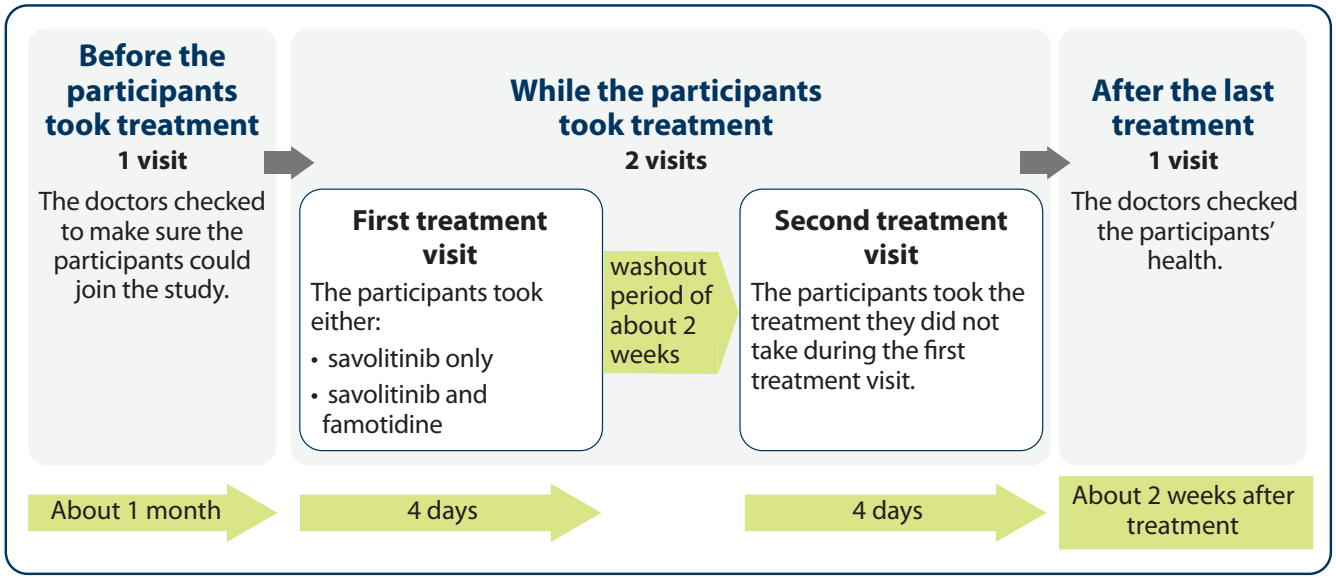
- did a physical examination
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

While the participants took treatment, they visited their study site 2 times over the course of about 1 month. Both visits lasted 4 days. During each visit, the participants took their treatment in an order that was randomly chosen.

There was a "washout period" of about 2 weeks in between the 2 visits. During this time, the participants did not take any study treatment and did not take certain medicines. This means that their bodies had time to process all of the study treatments, and any medicines in their blood had "washed out" of their bodies.

About 2 weeks after their last treatment, the participants visited their study site 1 more time. At this visit, the study doctors again checked the participants' health and asked them how they were feeling.

The chart below shows what happened during the study.



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 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.

How did savolitinib act in the body when taken with famotidine?

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

In these samples, they measured:

- the average total amount of the study drugs in the blood
- the average highest amount of the study drugs in the blood

The researchers compared the results from when the participants took savolitinib only to when they took savolitinib and famotidine. This information may help future researchers determine what other drugs can be given with savolitinib.

The researchers found that the average total amount of savolitinib in the blood was similar when taken with and without famotidine.

The researchers also found that the average highest amount of savolitinib in the blood was lower when taken with famotidine. But, the researchers did not consider this difference to be meaningful.

What medical problems happened during the 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 drugs. 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 drugs. 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 the study drugs.

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.

Did any adverse reactions happen during this study?

There were 18.8% of participants who had adverse reactions during the study that the study doctors thought might be related to savolitinib. This was 3 out of 16 participants.

None of the participants had adverse reactions during the study that the study doctors thought might be related to famotidine.

None of the participants left the study due to adverse reactions.

What serious adverse reactions happened during this study?

None of the participants had serious adverse reactions during this study.

None of the participants died due to serious adverse reactions during this study.

What adverse reactions happened during this study?

There were 2 different adverse reactions that happened during this study. The study doctors thought that each adverse reaction might be related to savolitinib:

- A small increase in transaminase levels in the blood, which is a sign of possible liver damage, happened in 12.5% of participants. This was 2 out of 16 participants. By the end of the study, the transaminase levels in these participants returned to normal.
- Headache happened in 6.3% of participants. This was 1 out of 16 participants.

How has this study helped patients and researchers?

This study helped researchers learn how savolitinib acted in the body in healthy male participants when taken with and without famotidine.

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 savolitinib 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 **"NCT04179071"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5084C00005"** into the search box, and click **"Find a Study"**.

Full Trial Title: An Open-Label, Randomised, Two Part, Two Treatment Crossover Study in Healthy Subjects to Assess the Pharmacokinetics of Savolitinib when Administered Alone and in Combination with Famotidine

AstraZeneca Protocol Number: D5084C00005

AstraZeneca AB sponsored this study and has its headquarters at 151 85 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.