Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca AB

Drug Studied: Osimertinib and fexofenadine

Short Study Title: A study to learn how fexofenadine acts in the body when taken alone compared to when taken with osimertinib, and if the 2 drugs are safe to take together

Thank you!

Thank you for taking part in the clinical trial for the drugs osimertinib and fexofenadine. The study started in March 2017 and ended in July 2017.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study with you and the public. An independent, nonprofit organization called CISCRP helped prepare this summary of the study results. We hope it helps you understand and feel proud of your important role in medical research.

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

Why was the research needed?

Researchers wanted to find out if osimertinib affected how fexofenadine acted in the body. Both of these drugs are commonly used on their own, but researchers wanted to know how they acted when they were taken together. Osimertinib is an approved cancer drug, and fexofenadine is an approved allergy drug.

In this study, the researchers also wanted to find out if the participants had any medical problems during the study. This information is important to know before other drugs that are similar to fexofenadine can be taken together with osimertinib.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participant knew what the participant was taking.

All participants in this study took fexofenadine and osimertinib. Both of the drugs were taken by mouth in tablet form.

What happened during the study?

Before the study started, the study doctors did a physical examination to make sure participants could join the study. They also took blood and urine samples and checked the participants’ heart health using an electrocardiogram also known as an ECG.

This study had 2 parts. All participants were in both parts.

Part 1 lasted 4 days, and all the participants visited their study site 5 times. They visited once on the day before Part 1 began, and then once each day during the 4-day period of Part 1. They took 1 dose of fexofenadine alone at their first visit. Then, study doctors checked the health of participants at each of the next 4 visits.

Part 2 lasted 42 days, and all the participants visited their study site 12 times. They took doses of osimertinib alone and both drugs together during these visits. Study doctors checked the health of participants during these 12 visits.

About 1 month after Part 2 ended, participants visited their study site once for a follow-up examination.

What were the study results?

This is a summary of the main results from this study overall. The results each individual participant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it also can be found on these websites.

How did fexofenadine act in the body when taken with osimertinib?

Researchers wanted to find out how fexofenadine acted in the body when taken with osimertinib compared to when the drugs were taken separately. So, study doctors took blood samples from the participants at different times during the study. Then, the researchers measured the average amount and the highest amount of both drugs in the blood.

In general, researchers found that the average and highest amounts of fexofenadine were greater when participants took osimertinib and fexofenadine together compared to when they took fexofenadine alone.

What medical problems did participants have?

The medical problems participants have during clinical studies that the doctors think might be related to the study drugs are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study 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.

The adverse reactions that happened in this study are not in this summary because there was a very small number of participants. Leaving this information out helps protect their identities. The websites listed at the end of this summary may have other information about medical problems that happened in this study.

How has this study helped patients and researchers?

This study helped researchers compare how fexofenadine acted in the body when taken with osimertinib.

The results presented here are for a single study. 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 1 study. Other studies may provide new information or different results.

Further clinical studies with osimertinib are planned or ongoing.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If a full report of the study results is available, it also can be found there.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT02908750"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home & Search"**, then type **"2016-002525-11"** in the search box and click **"Search"**.

The full title of your study is: An Open-label, Non-randomised, Phase I Study to Assess the Effect of Single and Multiple Oral Doses of Osimertinib (TAGRISSO™) on the Pharmacokinetics of a P-glycoprotein Probe Drug (Fexofenadine) in Patients with Advanced EGFRm NSCLC that have Progressed on a Prior EGFR-TKI Regimen

The protocol number of your study is: D5160C00036

AstraZeneca AB sponsored this study and has its headquarters at 1800 Concord Pike, Wilmington, DE 19850.

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 participants.