Clinical Study Results

Research Sponsor: AstraZeneca

Drug Studied: Osimertinib

Study Title: A study to learn how osimertinib acts in the bodies of patients with advanced solid tumors and damaged or healthy kidneys, and if osimertinib is safe to take for these patients

Thank you!

Thank you to the participants who took part in the clinical study for the study drug osimertinib. AstraZeneca 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 doctor or staff at your study site.

What is happening with the study now?

The study started in May 2017 and ended in September 2018. The study included 16 participants in France, the Republic of Korea, and Spain.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers are looking for a better way to treat patients with advanced solid tumors who also have damaged kidneys. “Advanced” means that the cancer cells have spread to other parts of the body. A solid tumor is a type of cancer that can form in different organs in the body.

In this study, the researchers wanted to find out how osimertinib acts in the bodies of participants who had advanced solid tumors and damaged or healthy kidneys. The researchers also wanted to find out if the participants had any medical problems during the study.

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

- Was the amount of osimertinib in the blood similar for participants with damaged kidneys and participants with healthy kidneys?
- 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 that help find out how osimertinib should be taken by patients with damaged kidneys.

The researchers asked for the help of men and women with advanced solid tumors. The participants in the study were 59 to 88 years old when they joined.

Some of the participants had damaged kidneys, and some had healthy kidneys. When the study started, there were 7 participants with damaged kidneys and 9 participants with healthy kidneys.

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 of the participants took osimertinib. They took it as a pill by mouth. Each dose of osimertinib was measured in milligrams, also called mg.

What happened during the study?

Before participants took osimertinib, the doctors did tests and exams to make sure they could join the study. The doctors checked the participants’ tumors, kidneys, and overall health.

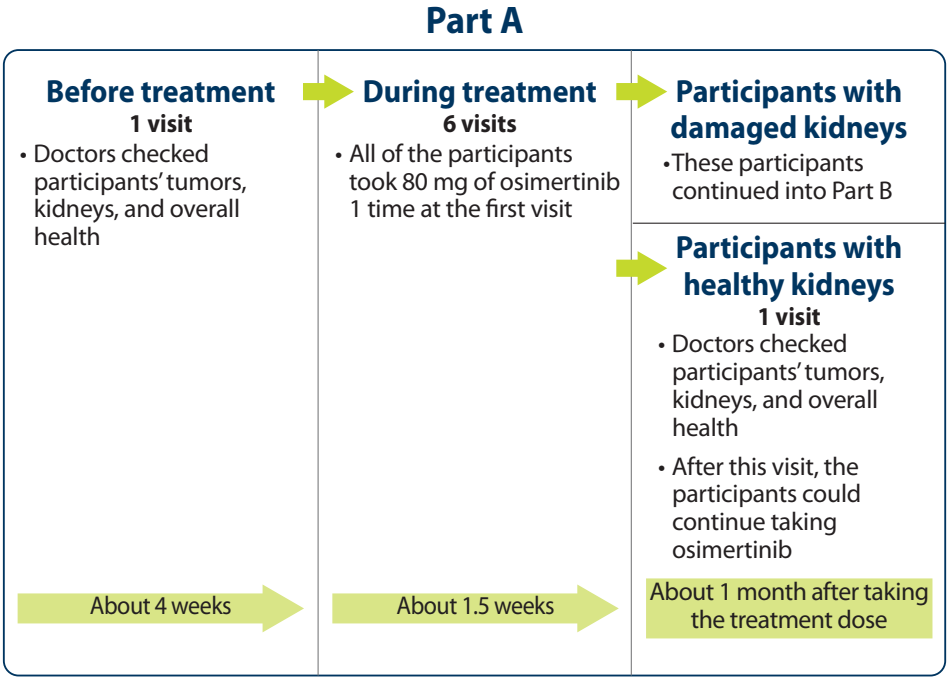
This study had 2 parts.

In Part A, the participants visited their study site 6 times during treatment. At the first treatment visit, all of the participants took one 80 mg dose of osimertinib. At each visit, the doctors took blood to measure the amount of the drug in the participants' blood. They also checked the participants' overall health.

The participants with damaged kidneys continued into Part B, where the doctors continued to check the participants' tumors, kidneys, and overall health. The participants with healthy kidneys did not continue into Part B, but could continue taking osimertinib according to their doctor's recommendation.

There were 7 participants in Part A with damaged kidneys, but 1 of these participants left the study before Part B. So, the researchers could only study the overall results for 6 of the 7 participants for Part B.

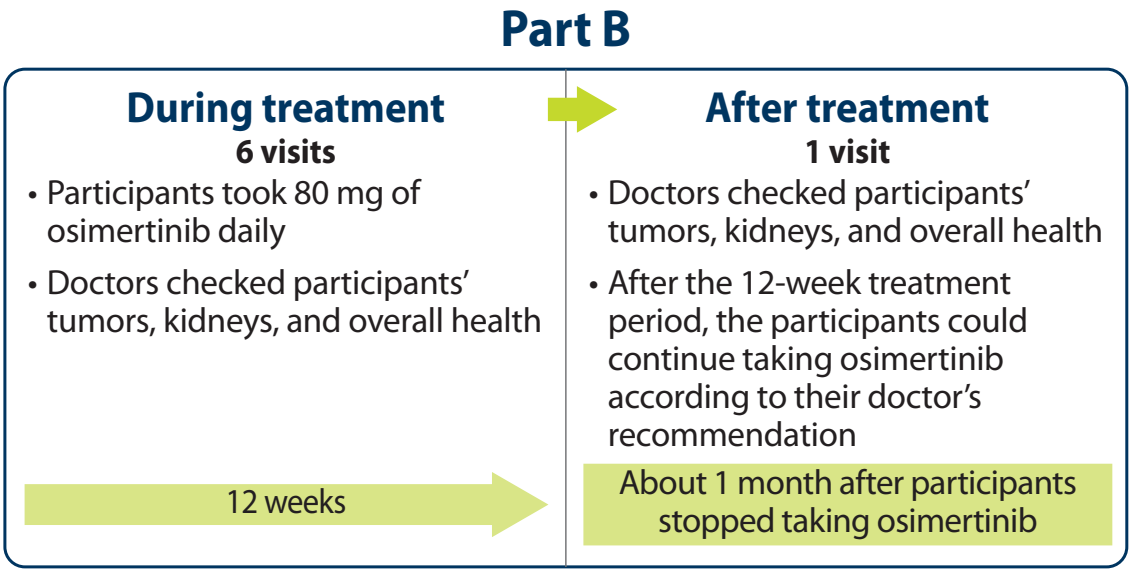
The chart below shows how Part A of the study was done.



In Part B, the participants visited their study site 6 times over the course of 12 weeks.

During this time period, they took one 80 mg dose of osimertinib daily. At the end of Part B, the participants visited their study site 1 more time so the doctors could check their tumors, kidneys, and overall health.

The chart below shows how Part B of the study was done.



What were the results of the study?

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.

Researchers look at the results of many studies to decide which treatment works best and is 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 a full report of the study results.

Was the amount of osimertinib in the blood similar for participants with damaged kidneys and participants with healthy kidneys?

No. The average and highest amounts of osimertinib in the blood were higher in the participants with damaged kidneys compared to the participants with healthy kidneys. But, because of the small number of participants in the study, the researchers did not think these differences were meaningful.

To answer this question, the researchers measured and compared the average and highest amounts of osimertinib in participants' blood throughout Part A. The average osimertinib amount was measured in nanomole hours per liter, also called nmol•h/L. The highest osimertinib amount was measured in nanomoles per liter, also called nmol/L.

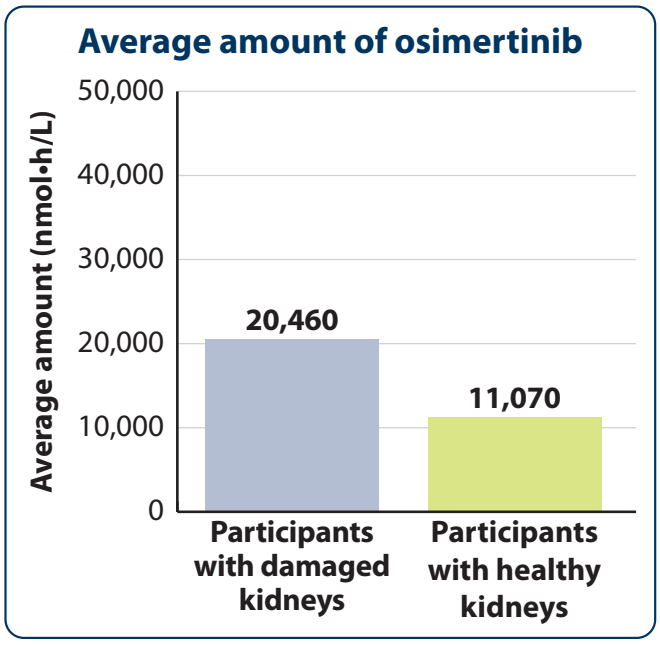
The average amount of osimertinib in the blood in Part A was:

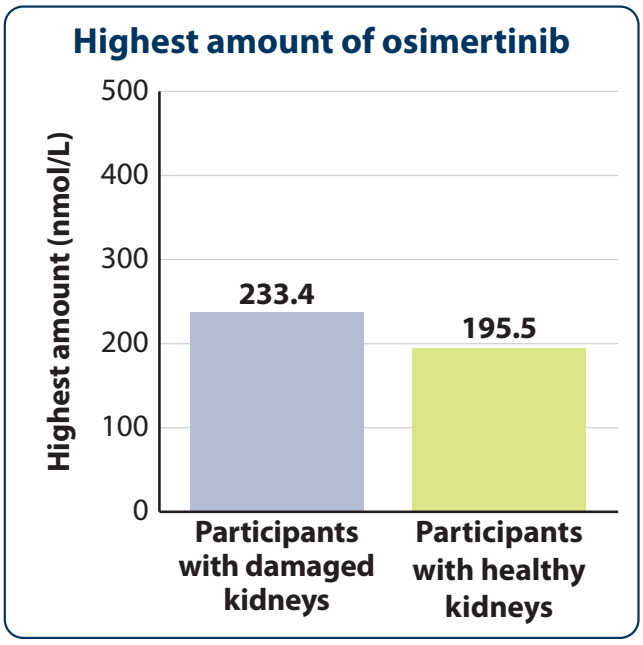
- 20,460 nmol•h/L in participants with damaged kidneys
- 11,070 nmol•h/L in participants with healthy kidneys

The highest amount of osimertinib in the blood in Part A was:

- 233.4 nmol/L in participants with damaged kidneys
- 195.5 nmol/L in participants with healthy kidneys

The figures below show these results.





What medical problems did the participants have 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 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.

The websites listed at the end of this summary may have other information about the adverse reactions or other medical problems that happened during this study.

How many participants had serious adverse reactions?

None of the participants had serious adverse reactions.

None of the participants died because of adverse reactions.

How many participants had adverse reactions?

In Part A:

- 22.2% of the participants with healthy kidneys had adverse reactions. This was 2 out of 9 participants.
- 28.6% of the participants with damaged kidneys had adverse reactions. This was 2 out of 7 participants.

In Part B:

- 50.0% of the participants had adverse reactions. This was 3 out of 6 participants.

None of the participants in either part stopped treatment because of adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction during the study was nausea. The table on the next page shows the adverse reactions that happened during the study.

Adverse reactions			
	Part A Participants with healthy kidneys (out of 9 participants)	**Part A Participants with damaged kidneys (out of 7 participants)**	**Part B Participants with damaged kidneys (out of 6 participants)**
Nausea	11.1% (1)	14.3% (1)	16.7% (1)
Decreased weight	11.1% (1)	14.3% (1)	0.0% (0)
Dry mouth	11.1% (1)	0.0% (0)	0.0% (0)
Decrease in appetite	0.0% (0)	0.0% (0)	16.7% (1)
Decrease in overall health	0.0% (0)	0.0% (0)	16.7% (1)
Diarrhea	0.0% (0)	0.0% (0)	16.7% (1)
Dry nose	0.0% (0)	0.0% (0)	16.7% (1)
Dryness in different parts of the body (a sign of dehydration)	0.0% (0)	0.0% (0)	16.7% (1)
Eye irritation	0.0% (0)	0.0% (0)	16.7% (1)
Feeling weak	0.0% (0)	0.0% (0)	16.7% (1)
Hallucinations	0.0% (0)	0.0% (0)	16.7% (1)
Infection near the fingernails or toenails	0.0% (0)	0.0% (0)	16.7% (1)

How has this study helped patients and researchers?

This study helped researchers learn how osimertinib acts in the bodies of patients with both advanced solid tumors and damaged or healthy kidneys, and if osimertinib is safe to take for these patients.

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 updated 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.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT02923947"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5160C00035"** into the search box, and click **"Find a Study"**.

Full Trial Title: An Open-label, Non-randomised, Multicentre, Phase I Study to Assess the Pharmacokinetics, Safety and Tolerability of Osimertinib (TAGRISSO) Following a Single Oral 80 mg Dose to Patients with Advanced Solid Tumours and Normal Renal Function or Severe Renal Impairment

AstraZeneca Protocol Number: D5160C00035

AstraZeneca sponsored this study and has its headquarters at 1800 Concord Pike in Wilmington, Delaware.

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.

CISCRP
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