

Clinical Trial RESULTS



Research Sponsor: AstraZeneca AB

Drug Studied: AZD9496

National Clinical Trial #: NCT02780713

Protocol #: D6090C00005

Study Date: June 2016 to September 2016

Short Study Title: A study in healthy participants to see how different forms of AZD9496 act in the body and if they cause medical problems

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 drug AZD9496. This drug is being developed to treat breast cancer. You and all of the participants helped researchers learn how AZD9496 acts in the body and if the drug causes medical problems.

AstraZeneca AB, 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 prepared this summary of the study results for you with the help of a medical writing organization. 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.

What has happened since my study ended?

Your study started in June 2016 and ended in September 2016. It included 14 participants at 1 study 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 drug can be approved, research must be done to show that it is safe and effective. The first step in studying a new drug is to test it in healthy people, or in people without any serious health problems.

Researchers in this study were interested in finding a better way to treat breast cancer. The study drug, AZD9496, is being developed to treat this disease.

Researchers wanted to know:

- How did AZD9496 act in the body?
- What medical problems did participants have after taking AZD9496?

What kind of study was this?

Your study was an “open-label” study. This means that both the study staff and participants knew what treatment each participant took.

In this study, all participants took AZD9496. There were 4 treatments of AZD9496 that were taken in capsule form. In a capsule, the study drug has an outer covering made of gelatin.

The other treatment of AZD9496 was taken in tablet form. In a tablet, the study drug is in a solid form without a covering.

Your study included 14 healthy men who were 40 to 58 years old.

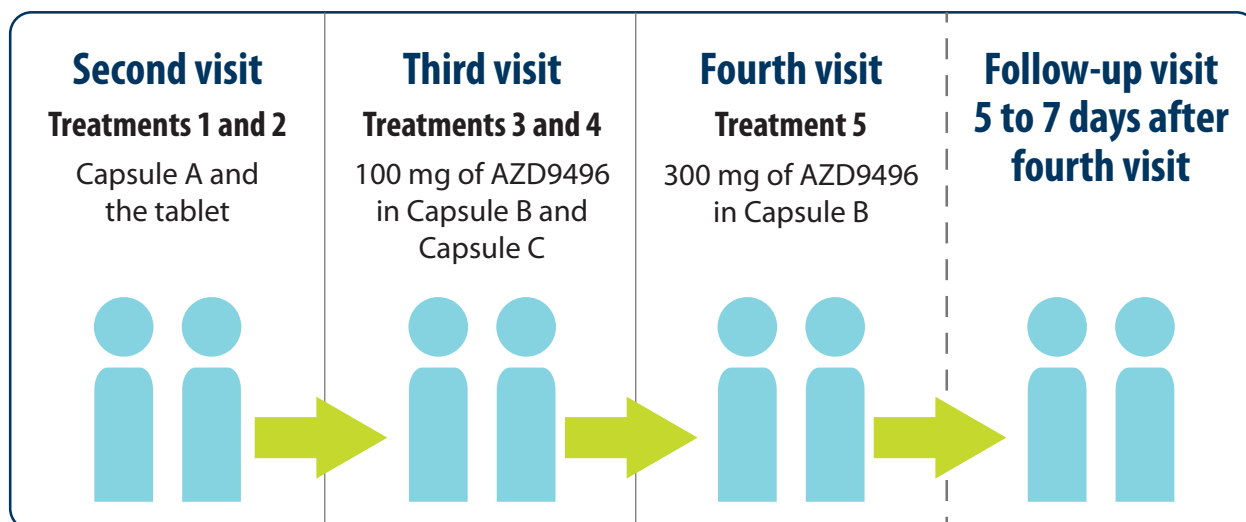
What happened during the study?

You and the other participants were in the study for up to 16 weeks.

Before the study started, study doctors did tests to check on your health and asked you questions to make sure you could join the study. They did a physical examination, which included checking your height, weight, and body temperature. They also tested samples of your urine and blood to check your overall health, and did an electrocardiogram, or ECG, to check your heart health. Researchers also asked about your medical history, how you were feeling, and what medicines you were taking.

You and all of the other participants who finished the study took all 5 AZD9496 treatments. Four of the treatments were in capsule form using 1 of 3 formulas: Capsule A, Capsule B, or Capsule C. The other treatment was AZD9496 in tablet form. Participants took the 5 treatments in the order listed below:

- Capsule A - 100 milligrams, or mg, of AZD9496
- Tablet - 100 mg of AZD9496
- Capsule B - 100 mg of AZD9496 in a second type of capsule
- Capsule C - 100 mg of AZD9496 in a third type of capsule
- Capsule B - 300 mg of AZD9496



During the study, study doctors did tests to make sure the participants were still healthy.

There was a 14-day “washout period” between the second and third visits. During the washout periods, participants were not allowed to take certain medications. This means that when participants took the next study treatments, all medications had been processed and “washed out” of their bodies. There was another washout period in between the third and fourth visit.

At the end of the study, participants returned to the study site for a follow-up visit 5 to 7 days after the last treatment. During this visit, study doctors took more blood and urine samples and asked participants how they were feeling. Researchers also did an ECG to check participants’ heart health and did a full physical examination.

What were the study results?

Below is a summary of the results of some of the questions the researchers asked during this study. 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 AZD9496 are currently planned.

How did AZD9496 act in the body?

Researchers wanted to know how the study drug acted in the body. So they measured the average amount of AZD9496 in the blood for all of the treatments. Researchers compared the 3 different types of capsules to the tablet.

When researchers compared the 100-mg capsules to the tablet, they found that:

- The average amount of AZD9496 in participants' blood was higher for the tablet than for any of the capsules.
- The average amount of AZD9496 in the blood for Capsule A was 31.8% of the average amount for the tablet.
- The average amount of AZD9496 in the blood for Capsule B was 54.2% of the average amount for the tablet.
- The average amount of AZD9496 in the blood for Capsule C was 41.2% of the average amount for the tablet.

When researchers compared the 2 Capsule B doses, they found that:

- The average amount of AZD9496 in the blood for the 300-mg dose was 114.2% of the average amount for the 100-mg dose.

What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are studied, researchers keep track of all medical problems that participants develop during the study. These medical problems are called “adverse events”. They may or may not be caused by the study drug.

How many participants developed medical problems during the study?

The table below shows how many participants in each treatment group had medical problems. None of the participants stopped taking the study drug because of a medical problem. Researchers do not think the study drug caused any of the medical problems.

	Capsule A - 100 mg of AZD9496 (Out of 14 participants)	Tablet - 100 mg of AZD9496 (Out of 14 participants)	Capsule B - 100 mg of AZD9496 (Out of 12 participants)	Capsule C - 100 mg of AZD9496 (Out of 12 participants)	Capsule B - 300 mg of AZD9496 (Out of 12 participants)
How many participants developed medical problems?	2 (14.3%)	1 (7.1%)	1 (8.3%)	0 (0.0%)	1 (8.3%)

How many participants developed serious medical problems?

A medical problem is considered serious when it's life-threatening, causes lasting problems, or needs hospital care. No participants died in your study, and no participants developed serious medical problems. No safety concerns were raised during this study.

What were the most common medical problems in the study that were not serious?

The table below shows all of the medical problems that were not serious that occurred in at least 1 participant in each treatment group.

Medical problems that were not serious	Capsule A - 100 mg of AZD9496 (Out of 14 participants)	Tablet - 100 mg of AZD9496 (Out of 14 participants)	Capsule B - 100 mg of AZD9496 (Out of 12 participants)	Capsule C - 100 mg of AZD9496 (Out of 12 participants)	Capsule B - 300 mg of AZD9496 (Out of 12 participants)
Bone and muscle pain	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)
Ringworm on the body	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)
Back pain	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Reddening of the skin	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Runny nose	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Where can I learn more about the study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/NCT02780713.

Official study title: A Study to Assess the Pharmacokinetics and Safety of Different Forms and Formulations of AZD9496 in Healthy Subjects (PK)

AstraZeneca AB, the sponsor of this study, has its headquarters in Södertälje, Sweden.

The phone number for the AstraZeneca Information Center is 1-877-240-9479.

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which 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.



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.

CISCRP
One Liberty Square, Suite 510
Boston, MA 02109
1-877-MED-HERO
www.ciscrp.org