Clinical Trial RESULTS

AstraZeneca

Research Sponsor: AstraZeneca AB
Drug Studied: AZD9977
National Clinical Trial #: NCT02484729
Eudra CT #: 2015-000877-11
Protocol #: D6400C00001
Study Date: July 2015 to November 2015
Short Study Title: A study in healthy males to investigate a new drug for the potential treatment of chronic kidney disease

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 study drug AZD9977. AZD9977 is a new drug being developed to treat kidney disease, including kidney disease from diabetes. You and all of the participants helped researchers learn how AZD9977 affects the body.

Astra Zeneca 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 and a medical writing organization called Synchrogenix prepared this summary of the study results for you. 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.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

WHAT'S HAPPENED SINCE MY STUDY ENDED?

This study started in July 2015 and ended in November 2015. It included 70 participants at 1 study site in the United Kingdom. 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 medicine can be approved, research studies must be done to show that it is safe and effective. The first step in studying a new medicine is to test it in healthy volunteers, before testing it in people with the disease the medicine will treat.

Researchers in this study tested a drug called AZD9977 as a possible treatment for chronic kidney disease. They wanted to compare the effects of different doses of AZD9977 in healthy adult males. By using an electronic capsule called IntelliCap, researchers also wanted to learn how AZD9977 was absorbed in the body. IntelliCap releases medicine when researchers want it to and can also be tracked so researchers know where AZD9977 is in the body at all times.

Researchers wanted to know:

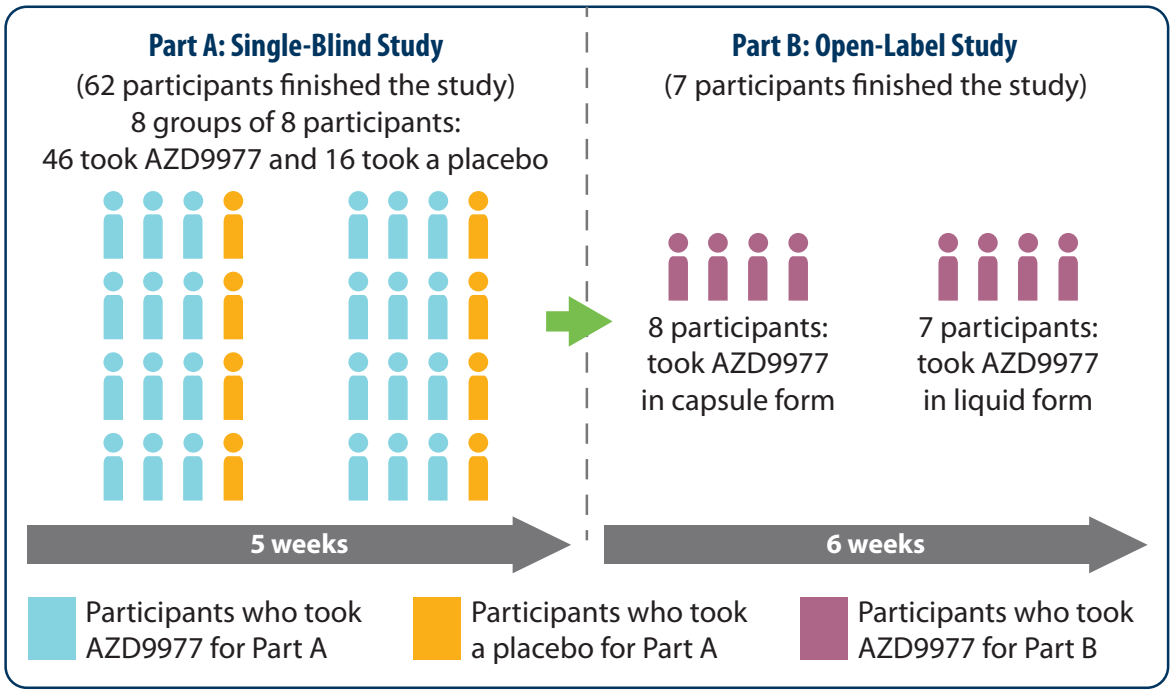
- How does the human body process AZD9977?
- How is AZD9977 absorbed in the body in participants who take it in capsule form compared to liquid form?
- How safe is AZD9977 to take and what medical problems did participants have?

This study had 70 healthy men between the ages of 20 and 48 years.

WHAT KIND OF STUDY WAS THIS?

Part A of this study was a "single-blind" study. "Single-blind" means that researchers knew what participants were taking but the participants did not know. Part B of this study was an "open-label" study. "Open-label" means that both researchers and participants knew what participants were taking. All participants took either AZD9977 or a placebo. A placebo looks like a real drug but has no actual medicine in it. Researchers use placebos to make sure the study drug actually works.

This study had 2 parts: Part A and Part B. The figure below shows how the study was done.



WHAT HAPPENED DURING THE STUDY?

Before starting this study, study doctors asked about each participant's medical history, did a physical exam and other tests, and took blood and urine samples to make sure each participant could participate.

Part A lasted 5 weeks. Eight participants were assigned to 1 of the 8 treatment groups:

- 5 milligrams (mg) of AZD9977 or a placebo
- 25 mg of AZD9977 or a placebo
- 100 mg of AZD9977 or a placebo
- 200 mg of AZD9977 or a placebo
- 400 mg of AZD9977 or a placebo
- 800 mg of AZD9977 or a placebo
- 800 mg of AZD9977 in split doses or a placebo
- 1200 mg of AZD9977 in split doses or a placebo

Two participants withdrew from Part A of the study before it began. Out of each group of 8 participants, 6 participants took their assigned dose of AZD9977 and 2 participants took a placebo. The first 6 participants who took AZD9977 got the 5 mg dose, and the last 6 participants got the 1200 mg dose.

Part B lasted 6 weeks. Eight new participants who were not in Part A were in this group and they got 2 doses of AZD9977:

- First dose: all 8 participants took 40 mg of AZD9977 inside an IntelliCap capsule
- Second dose: the 7 participants who finished the study took 40 mg of AZD9977 in liquid form

One participant did not complete Part B of the study. Part B had 1 group of 8 participants. When participants took the IntelliCap capsule of AZD9977 in the first dose, researchers programmed the capsule to slowly release AZD9977 over 12 hours. A second 40 mg dose of AZD9977 in liquid form was given to the same participants around 1 week later.

During the study, the study doctors and staff did an exam and other tests, and took blood and urine samples.

After the last treatment, participants had a final visit 5 to 7 days later so researchers could check their health.

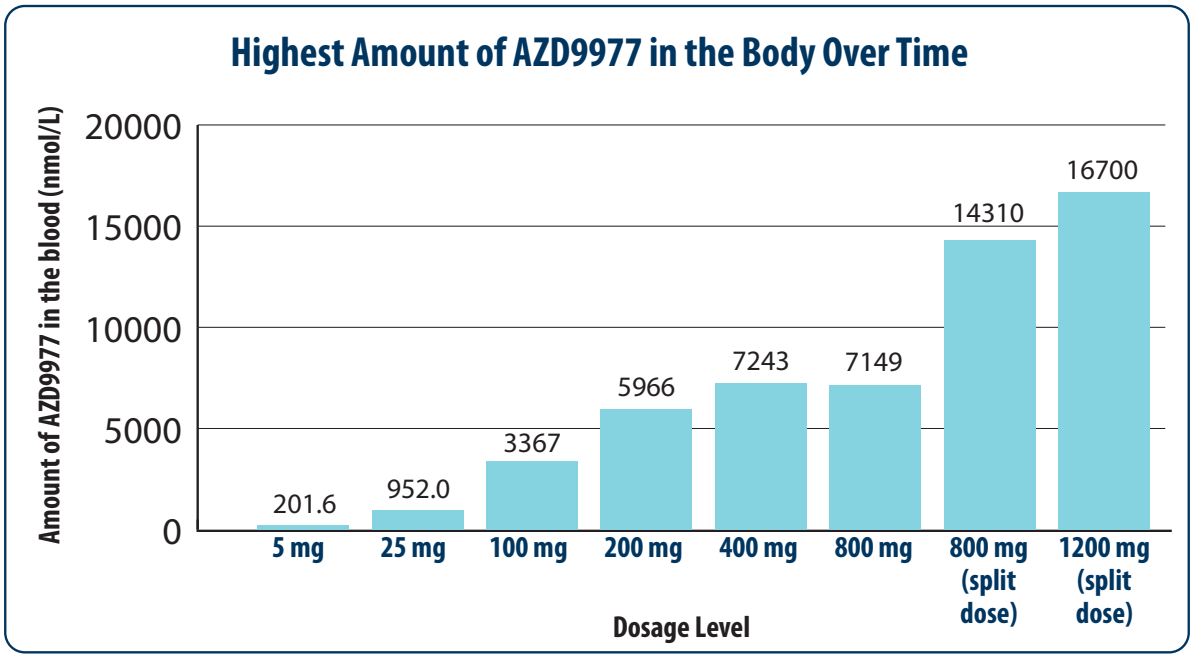
WHAT WERE THE STUDY RESULTS?

Below is a summary of the results of some of the questions 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 AZD9977 are not currently planned.

How does the human body process AZD9977 in lower doses compared to higher doses?

Researchers studied the results from Part A to answer this question. For doses from 5 to 400 mg, researchers found that as the dose of AZD9977 increased, the amount of AZD9977 that was absorbed in the body increased as well.

The figure below shows the highest amount of AZD9977 in participants' blood during the study.



Researchers also found the following:

- For doses from 5 to 800 mg, AZD9977 reached its highest amount in the blood anywhere from 30 minutes to 1 hour after the dose.
- Compared to the 200 mg dose, the 800 mg dose left 4 times the amount of AZD9977 in the body and the 1200 mg dose left 6 times the amount of AZD9977 in the body.

How is AZD9977 absorbed in the body in participants who take it in capsule form compared to liquid form?

Researchers studied the results from Part B to answer this question. They looked at how AZD9977 was absorbed in the body of participants who took the IntelliCap capsule form compared to a liquid form. They found the following:

Capsule:

- AZD9977 reached its highest amount in the blood at an average of just over 4 hours after the dose.

Liquid:

- AZD9977 reached its highest amount in the blood at an average of 45 minutes after the dose.
- The amount of AZD9977 in the blood was 1.5 times higher when taken as a liquid compared to the capsule form.
- The highest amount of AZD9977 in the blood over a certain measured time period was 4.9 times higher than in the capsule.

Together, these results show that the body absorbs more of AZD9977 in liquid form than in capsule form.

WHAT MEDICAL PROBLEMS DID PARTICIPANTS HAVE?

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

How many participants had medical problems?

In Part A, 11 out of the 46 participants (23.9%) who took AZD9977 and 7 out of the 16 participants (43.8%) who took placebo had at least 1 medical problem. No participants stopped taking the study drug because of medical problems.

The two tables below show how many participants had medical problems in Part A:

Medical Problems in Part A of the Study

	Placebo (Out of 16 participants)	5 mg AZD9977 (Out of 6 participants)	25 mg AZD9977 (Out of 6 participants)	100 mg AZD9977 (Out of 6 participants)	200 mg AZD9977 (Out of 5 participants)
How many participants had medical problems?	7 participants (43.8%)	1 participant (16.7%)	2 participants (33.3%)	2 participants (33.3%)	1 participant (20.0%)

Medical Problems in Part A of the Study *(Continued)*

	400 mg AZD9977 (Out of 6 participants)	800 mg AZD9977 (Out of 5 participants)	800 mg AZD9977, split doses (Out of 6 participants)	1200 mg AZD9977, split doses (Out of 6 participants)	AZD9977 Total (Out of 46 participants)
How many participants had medical problems?	2 participants (33.3%)	0 participants (0.0%)	2 participants (33.3%)	1 participant (16.7%)	11 participants (23.9%)

In Part B, 2 of the 8 participants (25.0%) who took AZD9977 in the capsule form and 2 of the 7 participants (28.6%) who took AZD9977 in liquid form had at least 1 medical problem. The table below shows how many participants had medical problems in Part B:

Medical Problems in Part B of the Study

	Capsule (Out of 8 participants)	Liquid (Out of 7 participants)
How many participants had medical problems?	2 participants (25.0%)	2 participants (28.6%)

What were the most common medical problems in Part A?

Among the 46 participants who took AZD9977 in Part A, the most common medical problems (more than 1 participant each) were dizziness (3 participants, 6.5%) and back pain (2 participants, 4.3%).

The two tables below show which dose groups of AZD9977 had these medical problems:

Most Common Medical Problems in Part A of the Study

Medical Problems	Placebo (Out of 16 participants)	5 mg AZD9977 (Out of 6 participants)	25 mg AZD9977 (Out of 6 participants)	100 mg AZD9977 (Out of 6 participants)	200 mg AZD9977 (Out of 5 participants)
Dizziness	1 participant (6.3%)	1 participant (16.7%)	1 participant (16.7%)	0 participants (0.0%)	1 participant (20.0%)
Back Pain	0 participants (0.0%)	0 participants (0.0%)	0 participants (0.0%)	1 participants (16.7%)	0 participants (0.0%)

Most Common Medical Problems in Part A of the Study *(Continued)*

Medical Problems	400 mg AZD9977 (Out of 6 participants)	800 mg AZD9977 (Out of 5 participants)	800 mg AZD9977, split doses (Out of 6 participants)	1200 mg AZD9977, split doses (Out of 6 participants)	AZD9977 Total (Out of 46 participants)
Dizziness	0 participants (0.0%)	0 participants (0.0%)	0 participants (0.0%)	0 participant (0.00%)	3 participants (6.5%)
Back Pain	1 participant (16.7%)	0 participants (0.0%)	0 participants (0.0%)	0 participants (0.0%)	2 participants (4.3%)

What were the most common medical problems in Part B?

In Part B of the study, the only medical problem that happened in more than 1 participant was the common cold. One out of 8 participants (12.5%) who took the capsule form and 1 out of 7 participants (14.2%) who took the liquid form had the common cold. The table below shows how many participants had medical problems in Part B of this study:

Medical Problems in Part B of the Study

Medical Problems	Capsule (Out of 8 participants)	Liquid (Out of 7 participants)
Common cold	1 participant (12.5%)	1 participant (14.2%)

How many participants in this study had serious medical problems?

A medical problem is considered serious when it is life-threatening, causes lasting problems or a participant needs hospital care.

No participants had serious medical problems.

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/results/NCT02484729.

Official study title: A Phase I, Randomized, Single-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, and Pharmacokinetics of AZD9977 Following Single Ascending Dose Administration to Healthy Male Subjects

Astra Zeneca AB, the sponsor of this study, is a member of the AstraZeneca group of companies and has its headquarters at 1800 Concord Pike, PO Box 15437, Wilmington, DE 19850.

The phone number for general information 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 trial 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.

CISCRP
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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.

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