Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca AB

Drug Studied: Sodium zirconium cyclosilicate

Study Title: A study to learn if sodium zirconium cyclosilicate can help lower potassium levels in the body

Thank you!

Thank you to the participants who took part in the clinical trial for the study treatment sodium zirconium cyclosilicate, also known as ZS.

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 for you.

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 October 2017 and ended in November 2017.

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

The study included 22 participants in China.

Why was the research needed?

Researchers are looking for a better way to treat patients who have high levels of potassium in the body. Before a treatment can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

Potassium is a substance found in food. The body uses potassium in several ways, including helping the heart to work normally. If the body's potassium levels are too high, the heart may not work normally. This can lead to several medical problems.

The body gets rid of potassium in urine through the kidneys. If the kidneys are not working normally, they might not be able to get rid of extra potassium to keep the body's potassium levels normal. ZS is a treatment that may help the body get rid of extra potassium to help lower these levels.

Researchers also wanted to know how ZS would affect the sodium levels in the urine of participants. Sodium is a substance found in food. The body needs sodium to maintain weight and blood pressure. But, too much sodium can cause weight gain and high blood pressure. The kidneys filter extra sodium out of the body and get rid of it through urine.

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

- How did ZS affect the potassium levels in the body?
- How did ZS affect the sodium levels in the urine?
- 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 if ZS can treat Chinese patients with high potassium levels.

In the study, the researchers asked for the help of healthy men and women. Everyone in the study was 22 to 53 years old when they joined.

What kind of study was this?

This was an "open-label" study. This means the researchers and the participants, doctors, or other study staff knew which treatment each participant received.

All of the participants in the study took 1 of the following treatments:

- 11 participants took 5 grams, also known as g, of ZS
- 11 participants took 10 g of ZS

Participants took ZS by mouth as a powder that was mixed with water.

A computer program was used to randomly choose the treatment each participant took. 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?

Before the study started, all the participants agreed to join. Then, the doctors checked to make sure the participants could join the study. The doctors:

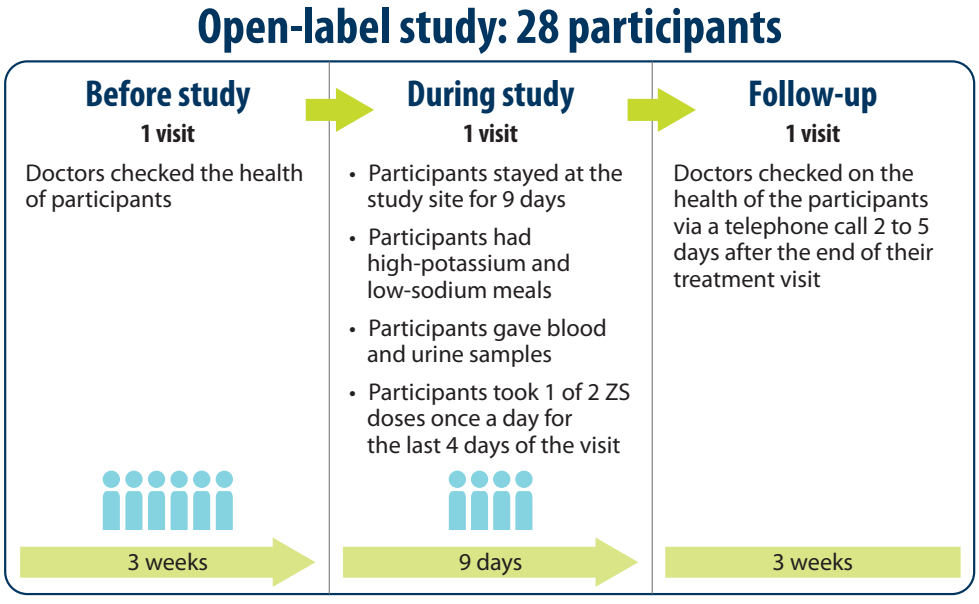
- did a physical examination
- took blood and urine samples
- checked the heart health of the participants using an electrocardiogram, also known as an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

During the study, the participants stayed at the study site for 9 days. During this time, the participants were given meals that had a high amount of potassium and a low amount of sodium in them. For the last 4 days of this visit, the participants took either 5 g or 10 g of ZS once a day with their breakfast.

Throughout the study, the researchers continued checking the health status of the participants and taking blood and urine samples. Researchers also continued doing ECGs to check heart health.

At the end of the study, the researchers called the participants to follow up with them. During this call, the researchers asked the participants about their overall health and how they were feeling.

The figure below shows how 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 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 change.

The websites listed at the end of this summary may have a full report of the study results.

How did ZS affect the potassium levels in the body?

The researchers found that ZS helped decrease the potassium levels in urine and in the blood.

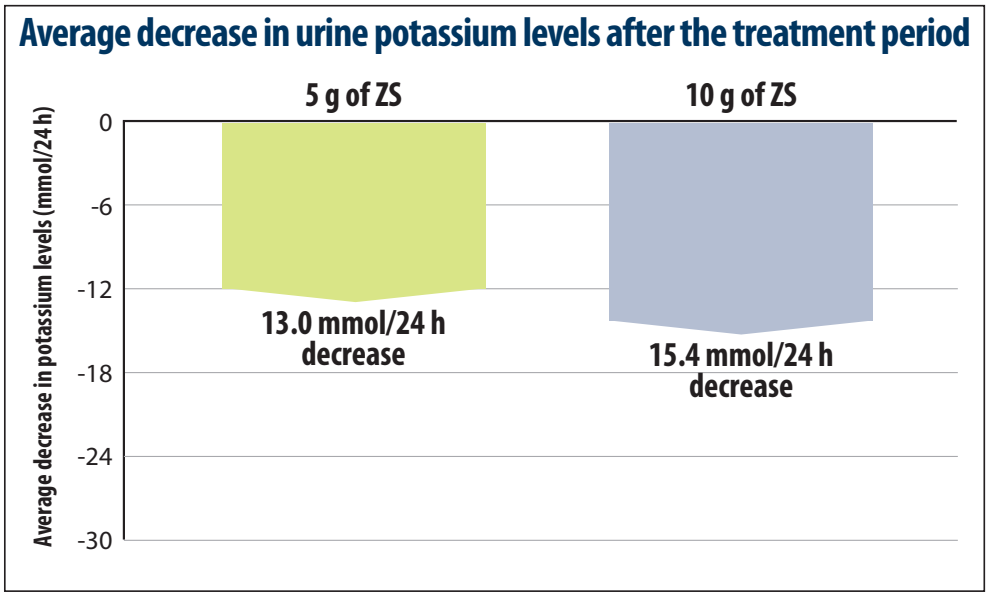
To answer this question, the researchers measured the potassium levels in the urine and blood of participants several times each day during the study. They compared the participants' urine and blood potassium levels before and after treatment.

The potassium levels were measured in millimoles a day, also known as mmol/24 h.

At the end of the treatment period, the researchers found that:

- The participants who took 5 g of ZS had an average decrease of 13.0 mmol/24 h in their urine potassium levels compared to before treatment.
- The participants who took 10 g of ZS had an average decrease of 15.4 mmol/24 h in their urine potassium levels compared to before treatment.

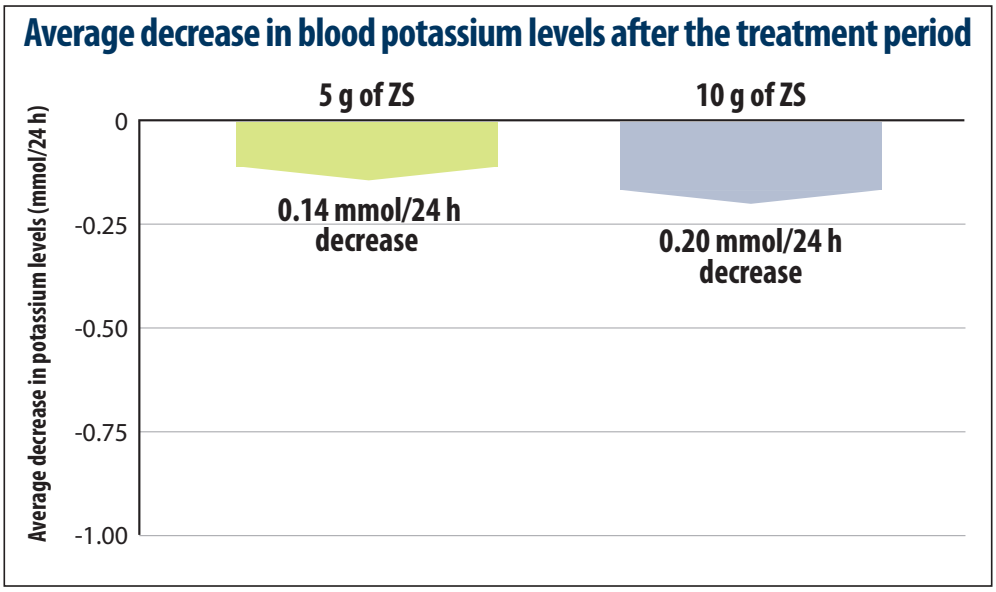
The figure below shows these results.



At the end of the treatment period, the researchers found that:

- The participants who took 5 g of ZS had an average decrease of 0.14 mmol/24 h in their blood potassium levels compared to before treatment.
- The participants who took 10 g of ZS had an average decrease of 0.20 mmol/24 h in their blood potassium levels compared to before treatment.

The figure below shows these results.



How did ZS affect the sodium levels in the urine?

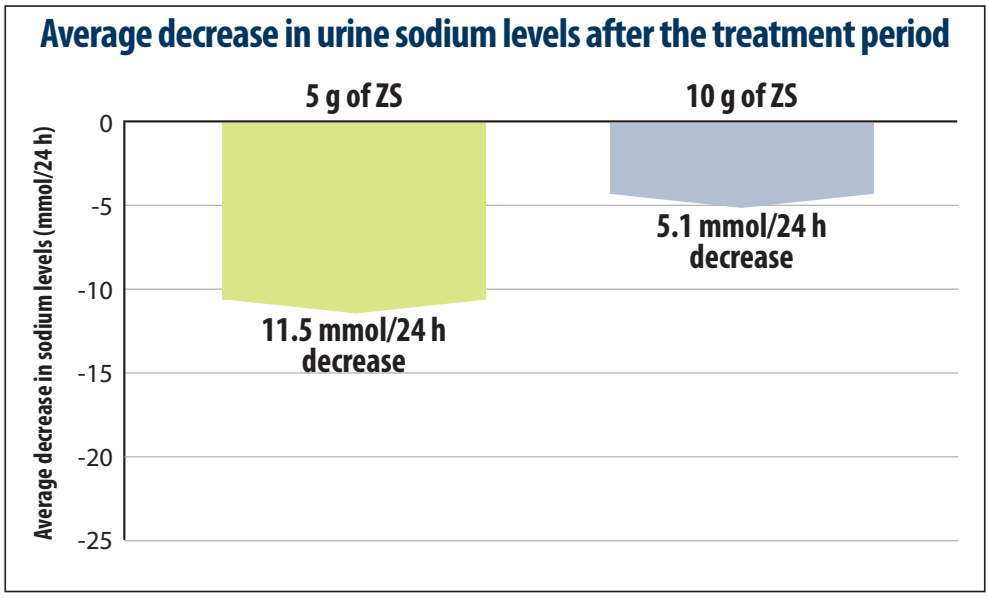
In general, the researchers found that ZS decreased sodium levels in the urine.

To answer this question, the researchers measured the sodium levels in the urine of participants several times each day during the study. They compared the participants' urine sodium levels before and after treatment. The sodium levels were measured in mmol/24 h.

At the end of the treatment period, the researchers found that:

- The participants who took 5 g of ZS had an average decrease of 11.5 mmol/24 h in their urine sodium levels compared to before treatment.
- The participants who took 10 g of ZS had an average decrease of 5.1 mmol/24 h in their urine sodium levels compared to before treatment.

The figure below shows 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 treatment. 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 treatment. A lot of research is needed to know whether a treatment causes an adverse reaction.

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.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

None of the participants had adverse reactions during the study.

How has this study helped patients and researchers?

These results helped the researchers learn more about ZS and if it can help lower potassium levels in the body.

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 ZS in Chinese patients are planned.

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 here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03283267"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D9483C00001"** into the search box and click **"Find a Study"**.

Full Trial Title: A Single-center Safety and Pharmacodynamic Study of Healthy Chinese Subjects Administered Sodium Zirconium Cyclosilicate (ZS)

AstraZeneca Protocol Number: D9483C00001

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.