

**Research Sponsor:** AstraZeneca AB

**Drug Studied:** Roxadustat

**Trial Purpose:** This trial was done to learn how roxadustat works and about its safety in people with low levels of iron in their blood from chronic kidney disease.

**Protocol Number:** D5741C00002

## Thank you

Thank you to the participants who took part in the clinical trial for the trial drug roxadustat.

All of the participants helped researchers learn more about roxadustat to help people with low levels of iron in their blood from chronic kidney disease.

AstraZeneca AB sponsored this trial and believes it is important to share the results of this trial with the participants and the public. AstraZeneca AB reviewed the results of this trial when it ended and created a report of those results. This is a summary of that report.

An independent non-profit organization called CISCRP helped prepare this summary of the trial results. We hope it helps the participants understand and feel proud of their important role in medical research.

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

# Overview of this trial



## Why was the research needed?

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Researchers are looking for a better way to treat low blood iron levels in people with chronic kidney disease. After a drug is approved for people to receive, researchers do more clinical trials to keep looking at how it works and how safe it is.



## What treatments did the participants receive?

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The participants in this trial received roxadustat or another treatment called recombinant human erythropoietin, which is also called “rHuEPO”.



## What were the results of this trial?

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The main question the researchers wanted to answer in this trial was:

### ► Did roxadustat affect how much iron got into the participants' blood compared with rHuEPO?

Overall, the differences between the groups were too small for the researchers to know if roxadustat affected how much iron got into the participants' blood compared with rHuEPO.

More details about the results of this trial are included later in this summary.



## What medical problems did the doctors report as possibly related to the trial treatment?

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There were 4.0% of participants who had medical problems that the trial doctors reported as possibly being related to the trial drug. This was 1 out of 25 participants. This participant had received roxadustat.

More details about the medical problems from this trial are included later in this summary.



## Where can I learn more about this trial?

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You can find more information about this trial on the websites listed on the last page. When a full report of the trial results is available, it also can be found on these websites.



## Who took part in this trial?

The researchers asked for the help of people with chronic kidney disease who had low levels of iron in their blood. Having low levels of iron in the blood is also called “anemia”, and chronic kidney disease is also called “CKD”.

The participants in this trial were 25 to 78 years old when they joined.

This trial included 9 males and 16 females in China.



## Why was the research needed?

Researchers are looking for a better way to treat anemia in people with CKD. After a drug is approved for people to receive, researchers do more clinical trials to keep looking at how it works and how safe it is.

CKD is a long-term kidney disease. People who have it slowly lose more and more kidney function over time. The kidneys filter the blood, and they are important for helping to keep the blood healthy and making sure that blood cells have enough iron. Blood cells need iron to be able to carry oxygen around the body.

When CKD is advanced, it is hard for the body to make enough new red blood cells and for the gut to absorb enough iron from food. This is known as anemia. Having anemia can make someone more at risk for infections and can lead to heart and lung problems.

Recombinant human erythropoietin and roxadustat are treatments that are already used for anemia in people with CKD. Recombinant human erythropoietin is also called rHuEPO. But, researchers think that rHuEPO only helps with anemia symptoms and doesn't prevent the cause of anemia.

Researchers think that roxadustat might prevent anemia by helping to make more red blood cells and helping the gut to absorb more iron from food. In this trial, the researchers wanted to find out if roxadustat affected how much iron got into the participants' blood compared with rHuEPO.



## What was the purpose of this trial?

This was a “Phase 4” trial. Researchers already did trials that showed roxadustat worked for the people with anemia from CKD who were in those trials. In this trial, the researchers wanted to find out more about how roxadustat works compared with rHuEPO.

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

- ▶ Did roxadustat affect how much iron got into the participants’ blood compared with rHuEPO?
- ▶ What medical problems did the doctors report as possibly related to the trial treatment?



## What treatments did the participants receive?





In this summary, “trial treatment” means anything the participants received as a part of the trial. This includes roxadustat and rHuEPO. Roxadustat is the treatment that the researchers wanted to learn more about.

The participants in this trial received roxadustat or rHuEPO. This was an “open-label” trial. This means the participants, researchers, trial doctors, and other trial staff knew what each participant was receiving.

A computer program was used to randomly choose the treatment each participant received. This was based on whether the participants needed dialysis or not, and if they had received rHuEPO before or not. Dialysis is a treatment for CKD that uses a machine to replace the function of the kidneys and filter the blood.

Using a computer program to choose the treatment each participant received helped make sure the groups were chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

The chart below shows the treatment plan for the participants.

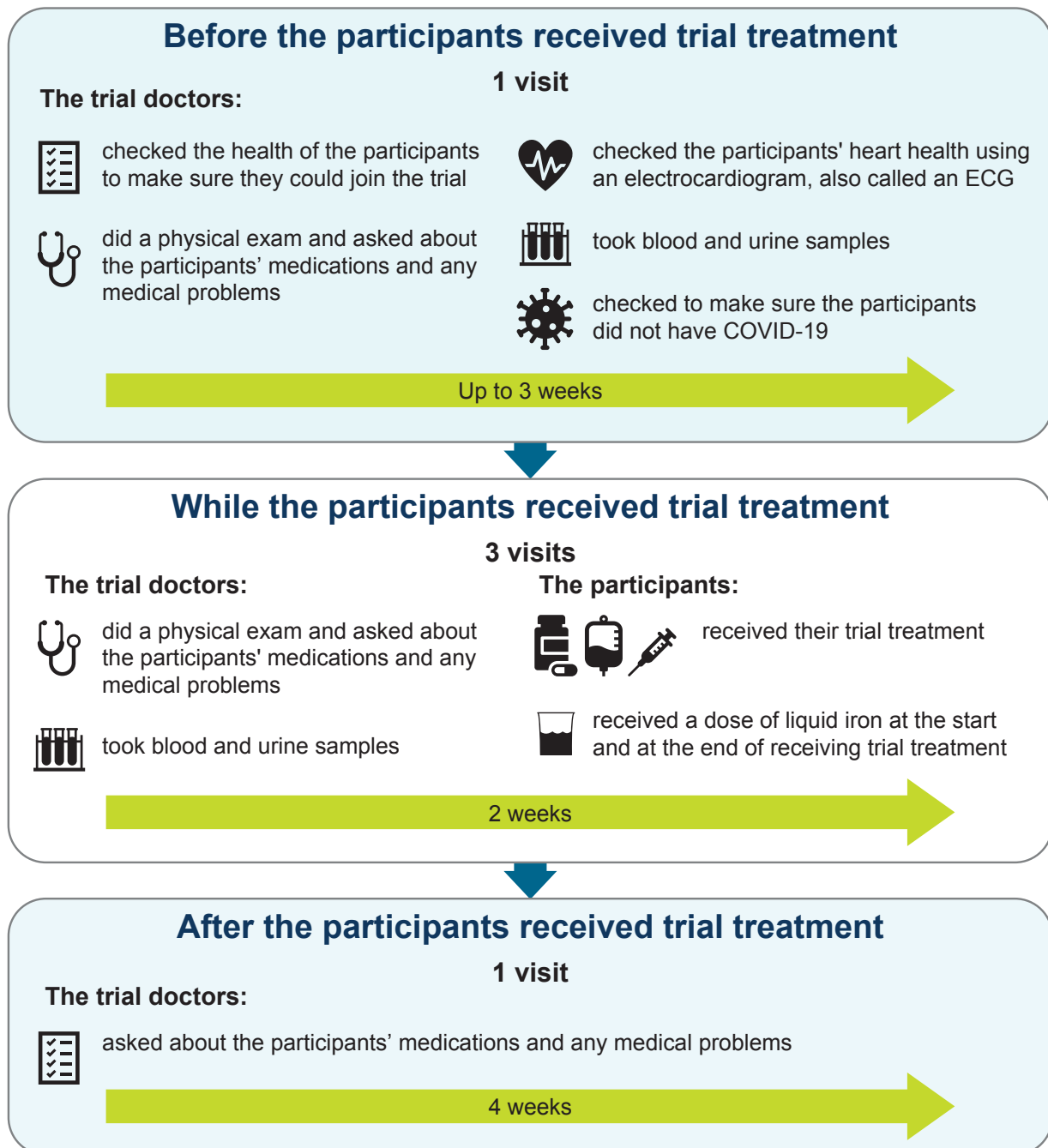
	Roxadustat	rHuEPO
	13 participants	12 participants
 	Tablets by mouth	Through a needle into a vein or into the skin
	3 times per week For 2 weeks total	2 or 3 times per week depending on the dose of rHuEPO they had received before joining the trial  For 2 weeks total



## What happened during this trial?

The participants were in the trial for about 9 weeks. But, the entire trial took 7 months to finish. The trial started in February 2021 and ended in October 2021.

The chart below shows what happened during the trial.







## What were the results of this trial?

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

Researchers look at the results of many trials to decide which treatments work best and are safest. Other trials may provide new information or different results. Always talk to a doctor before making any treatment changes.

### **Did roxadustat affect how much iron got into the participants' blood compared with rHuEPO?**

**No.**

To answer this question, the trial doctors gave the participants a dose of liquid iron. Then, they took blood samples to measure how much of the original amount of iron got into the participants' blood 3 hours later.

The researchers did this measurement before the participants received any treatment, and after 2 weeks of receiving treatment. The researchers calculated how much this measurement changed after 2 weeks of treatment. Then, they compared the results between the participants who took roxadustat and the participants who received rHuEPO.

Overall, the researchers found that there were some differences between the groups. But, the differences were too small for the researchers to conclude if roxadustat affected how much iron got into the participants' blood compared with rHuEPO.



## What medical problems did the doctors report as possibly related to the trial treatment?

This section is a summary of the medical problems that the participants had during this trial that the doctors reported as possibly related to the trial treatments. 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. The results from several trials are needed to decide if a treatment causes an adverse reaction.

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

### Did any adverse reactions happen during this trial?

There were 4.0% of participants who had adverse reactions in this trial. This was 1 out of 25 participants. This participant had received roxadustat.

	<b>Roxadustat</b> (out of 13 participants)	<b>rHuEPO</b> (out of 12 participants)
How many participants had serious adverse reactions?	none	none
How many participants had adverse reactions?	7.7% (1)	none
How many participants stopped receiving trial treatment due to adverse reactions?	none	none

## What serious adverse reactions happened during this trial?

None of the participants in this trial had serious adverse reactions.

## What adverse reactions happened during this trial?

The only adverse reaction that happened during this trial was **back pain**.



## What did researchers learn from this trial?

This trial helped researchers learn more about how roxadustat affects people with low levels of iron in their blood from chronic kidney disease.

Overall, the researchers found that there were some differences between how much iron got into the participants' blood after they received roxadustat compared with rHuEPO. But, the differences were too small for the researchers to conclude if roxadustat affected how much iron got into the participants' blood compared with rHuEPO.

Researchers look at the results of many trials to decide which treatments work best and are safest. This summary shows only the main results from this one trial. Other trials may provide new information or different results.

At the time this summary was made and approved by the sponsor, further clinical trials with roxadustat were planned.



## Where can I learn more about this trial?

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

- ▶ [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type **NCT04655027** into the **"Other terms"** search box, and click **"Search"**.
- ▶ [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type **D5741C00002** into the search box and click **"Find a Study"**.

**Full Trial Title:** ALTA1: An Open-Label, Randomized, Active-Controlled, Parallel Design, Multicenter Phase IV Study to Investigate the Effect of Roxadustat versus Recombinant Human Erythropoietin (rHuEPO) on Oral Iron Absorption in Chinese Patients with Anemia of Chronic Kidney Disease (CKD)

**AstraZeneca Protocol Number:** D5741C00002

**National Clinical Trials Number:** NCT04655027

**AstraZeneca AB** sponsored this trial and has its headquarters in Södertälje, Sweden.

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

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## Thank you

Clinical trial 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.

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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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