AstraZeneca

Clinical Study Results

Research Sponsor: MedImmune, a wholly owned subsidiary of AstraZeneca

Drug Studied: Cotadutide

Study Title: A study to learn how much cotadutide got into the blood when injected into different parts of the body in healthy participants

Protocol Number: D5670C00025

Thank you!

Thank you for taking part in the clinical study for the study drug cotadutide, also called MEDI0382.

AstraZeneca sponsored this study and believes 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 study doctor or staff at your study site.

Who took part in this study?

The researchers asked for the help of healthy men and women. The participants in this study were 22 to 59 years old when they joined.

The study included 36 participants, all in the United States.

Why was the research needed?

Researchers are looking for a different way to treat obesity. Before a drug can be approved for people to get it, researchers do clinical studies to find out how safe it is and how it works.

The study drug, cotadutide, is being developed to treat people who have obesity and type 2 diabetes. It works by reducing appetite and slowing digestion, which helps people feel full for longer. This may help people who have obesity to lose weight. Researchers also think that cotadutide can reduce blood sugar levels, which would help people who have type 2 diabetes.

In this study, the researchers wanted to find out more about how cotadutide acted in the blood of healthy participants. They wanted to learn how much cotadutide got into the blood when injected through a needle into different parts of the body.

What was the purpose of this study?

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

- How much cotadutide got into the participants' blood when injected into different parts of the body?
- What medical problems did the participants have during this study?

The answers to these questions are important to know before other studies can be done to find out if cotadutide helps improve the health of people who have obesity and type 2 diabetes.

What treatments did the participants take?

In this study, all of the participants got cotadutide through a needle under the skin. This is also known as a subcutaneous injection. All of the participants got injections into 3 different parts of their body during the study. This could be in the belly, arm, or thigh. The dose of each cotadutide injection was measured in micrograms, also known as µg.

There were 6 groups of participants, and each group got the injections in a different order. All the participants got the same dose of 100 µg of cotadutide.

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what order of injection each participant was getting.

A computer program was used to randomly choose the order that each participant would get their injections. 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.

The chart below shows the treatments that the participants got during the study.

	36 participants 6 groups of 6 participants
	1 injection each into the belly, arm, and thigh 100 µg of cotadutide in each injection
	Injections under the skin once a week, for around 3 weeks

What happened during this study?

The study started in September 2019 and ended in March 2020. The participants were in the study for about 10 weeks.

Before the participants got study treatment, they visited their study site 1 time. This part of the study lasted for 4 weeks. At this visit, the study doctors checked the participants' health to make sure they could join the study. The study doctors:

- did a physical exam and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG

The study doctors also did these tests and measurements throughout the study.

While the participants got study treatment, they visited their study site 3 times. This part of the study lasted nearly 3 weeks.

- At each of the 3 visits, the participants stayed overnight at the study site for 4 days.
- The participants got an injection of cotadutide on the second day of each study site stay.
- The participants got each injection in the morning after not eating or drinking for 8 hours overnight. After each injection, the participants waited 6 hours before eating.
- The researchers measured how much cotadutide was in the participants' blood. They did this on the day of each injection and for the next 2 days after each injection.

After the participants got study treatment, they visited their study site 1 time. This part of the study lasted about 4 weeks. At this visit, the study doctors checked the health of the participants.

What were the results of this 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 changes.

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

How much cotadutide got into the participants' blood when injected into different parts of the body?

To answer this question, the study doctors measured the amount of cotadutide in the participants' blood before and after they got each injection. The researchers then compared the average total amount of cotadutide that got into the participants' blood when it was injected into the belly and when it was injected into the arm or the thigh.

Overall, the researchers found that the average total amount of cotadutide in the participants' blood was:

- similar when it was injected into the arm compared to the belly
- smaller when it was injected into the thigh compared to the belly

What medical problems happened 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the study drug.

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.

All 36 participants got an injection into the belly, arm, and thigh. The adverse reactions shown below are grouped by these different parts of the body.

Did any adverse reactions happen during this study?

	Location of injection		
	Belly (out of 36 participants)	**Arm** (out of 36 participants)	**Thigh** (out of 36 participants)
How many participants had adverse reactions?	27.8% (10)	27.8% (10)	11.1% (4)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped taking study treatment due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)

What serious adverse reactions happened during this study?

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

None of the participants in this study died due to serious adverse reactions.

What adverse reactions happened during this study?

The most common adverse reaction was feeling sick.

The table below shows the adverse reactions that happened in during this study.

Adverse reactions			
	Location of injection		
Adverse reaction	**Belly** (out of 36 participants)	**Arm** (out of 36 participants)	**Thigh** (out of 36 participants)
Feeling sick	22.2% (8)	25.0% (9)	8.3% (3)
Vomiting	16.7% (6)	13.9% (5)	2.8% (1)
Pain in the belly	8.3% (3)	0.0% (0)	0.0% (0)
Dizziness	2.8% (1)	5.6% (2)	2.8% (1)
Diarrhea	2.8% (1)	2.8% (1)	0.0% (0)
Headache	2.8% (1)	2.8% (1)	0.0% (0)
Feeling faint	2.8% (1)	0.0% (0)	0.0% (0)
Fainting	2.8% (1)	0.0% (0)	0.0% (0)
Reduced appetite	0.0% (0)	0.0% (0)	2.8% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about how much cotadutide got into the blood in healthy participants when injected into different parts of 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 1 study. Other studies may provide new information or different results.

Further clinical studies with cotadutide are planned.

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 **"NCT04091373"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5670C00025"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase 1, Randomized, Open-label, Single Center, Three Period Cross-over Study to Evaluate the Pharmacokinetics of Single Dose Administration of Cotadutide in Healthy Subjects.

AstraZeneca AB Protocol Number: D5670C00025

National Clinical Trials number: NCT04091373

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

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

Thank you

Participants in clinical studies 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.

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