

Clinical Trial Results Summary

A clinical trial to learn about the safety and effects of QCZ484 in healthy people and people with mild hypertension

Thank you!

Thank you to the participants who took part in this clinical trial. Every participant helped to learn more about the trial drug **QCZ484**, also called **BW-00163**.

Novartis is the sponsor of this trial. We believe it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CQCZ484A02101
(previously BW-00163-1002)

Novartis drug studied: **QCZ484**,
also called **BW-00163**

Sponsor: Novartis

..... If you were a participant and have any
questions about the results, please talk
to your doctor or staff at the trial site.

..... This summary only shows the results of
a single clinical trial. Other clinical trials
may have different results.

What was the main purpose of this trial?

The purpose of this trial was to learn about the safety and effects of different doses of **QCZ484** for healthy people and people with **mild hypertension**. This trial was the first time that **QCZ484** was given to people.



Hypertension is also called **high blood pressure**. It happens when the force of blood pushing against the inside walls of blood vessels is higher than normal. This can raise the chance of serious health conditions, such as heart attack and stroke. In this trial, participants had mild high blood pressure based on their **systolic blood pressure**.



QCZ484 is a trial drug created to block the body from making a certain protein. This protein, called angiotensinogen or **AGT**, plays a role in high blood pressure. Researchers think lowering the level of AGT in the body could lower blood pressure.

Blood pressure is the force of blood pushing against the walls of the blood vessels. It has 2 numbers:

- **Systolic blood pressure** is the pressure when the heart beats. It is the first, or top, number of the blood pressure measurement.
- **Diastolic blood pressure** is the pressure when the heart rests between beats. It is the second, or bottom, number of the blood pressure measurement.



The trial's purpose was to answer this main question:

- What medical problems, also called adverse events, happened during this trial?

↳ **Adverse events** reported are any sign or symptom that participants had during this trial. Adverse events **may** or **may not** be caused by treatments in this trial.

How long was this trial?



The trial began in March 2023 and ended in July 2025. The participants started the trial on different dates.

This trial was designed to have 2 parts:

- **Part A:** First, the researchers tested increasing doses of **QCZ484** in different groups of **healthy participants** to find the doses to give in Part B. The researchers also carefully checked all the medical problems that happened during the trial to identify any that could cause changes in dosing.
- **Part B:** Then, researchers chose doses of **QCZ484** from Part A to give to **participants with high blood pressure**. These results let researchers know what other trials may be needed and what doses to use in the future.

At the end of this trial, Novartis created a report of the trial results. This summary is based on that report.

Who was in this trial?

Each participant took part in either Part A or Part B:



Part A: 34 healthy participants joined Part A – 21 males and 13 females. Participants’ ages ranged from 21 to 58 years. Their average age was 37 years.

The table below shows the number of participants by race.

Race of participants in Part A

2	American Indian or Alaska Native	3	Asian	25	White
1	Unknown	3	Other		



Part B: 25 participants with high blood pressure joined Part B – 15 males and 10 females. Participants' ages ranged from 32 to 66 years. Their average age was 54 years.

The table below shows the number of participants by race.

Race of participants in Part B

1 Native Hawaiian or
Other Pacific Islander

1 Asian

22 White

1 Other

The participants could take part in this trial if they did not have certain health conditions and had a **systolic blood pressure** that was:

- More than 90 millimeters of mercury (mmHg) or a diastolic blood pressure more than 60 mmHg for healthy participants in **Part A**
- Between 130 and 159 mmHg for participants with high blood pressure in **Part B**

56 participants from 2 countries received treatment.

The participants took part in:

- Australia | 50 participants
- New Zealand | 6 participants

What treatments did the participants receive?

The treatments in this trial were:



QCZ484 – received as an injection under the skin one time.

This trial looked at 4 different doses of **QCZ484**:

- 50 milligrams (mg)
- 150 mg
- 300 mg
- 600 mg



Placebo – received as an injection under the skin one time. It looks like the trial drug but does not have any drug in it. Researchers use a placebo to better understand the effect of a trial drug.

Researchers used a computer to randomly assign participants to their treatment.

Along with the treatments above, participants with high blood pressure could take other treatments to lower their blood pressure if needed, such as calcium channel blockers.

The participants, researchers, and trial staff did not know what treatment the participants were receiving. Some trials are done this way because knowing what treatment the participants receive can affect the results of the trial. Doing a trial this way helps to make sure that the results are looked at with fairness across all treatments.

What happened during this trial?

Before treatment

1 month



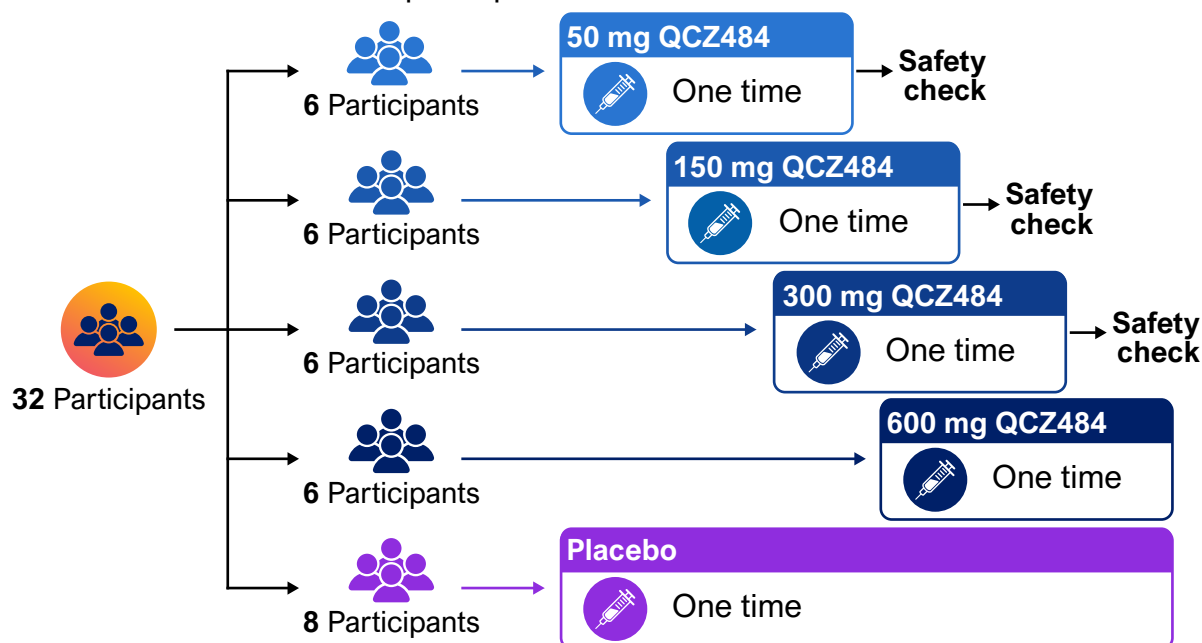
The trial staff checked to make sure the participants could be in this trial. 2 participants in Part A and 1 participant in Part B left the trial before receiving treatment.

During treatment

3 days

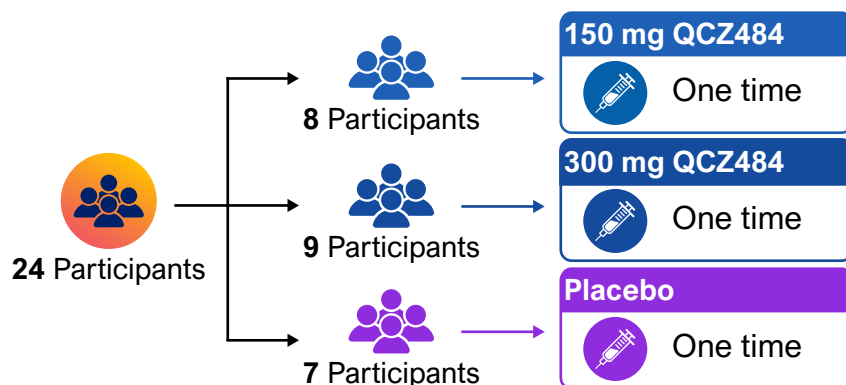


In **Part A**, 32 healthy participants were assigned to 1 of 5 treatments. The graphic below shows which treatment participants received:



Participants who received the lowest dose of **QCZ484** started treatment first, along with 2 participants who received **placebo**. The researchers checked for safety concerns before the next participants received a higher dose of **QCZ484** or **placebo**. They also measured the amount of **QCZ484** in the participants' blood.

In **Part B**, 24 participants with high blood pressure were assigned to 1 of 3 treatments. The graphic below shows which treatment participants received:





Trial staff checked participants for any medical problems for up to 11 months after receiving treatment.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They do this even if they think the adverse events are not related to the trial treatments.

Researchers need results from many trials to decide if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of treatment until 11 months after treatment.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, requires hospital care, or results in death

Treatments in the trial **may** or **may not** cause adverse events.



Part A: 22 out of 32 healthy participants had adverse events.

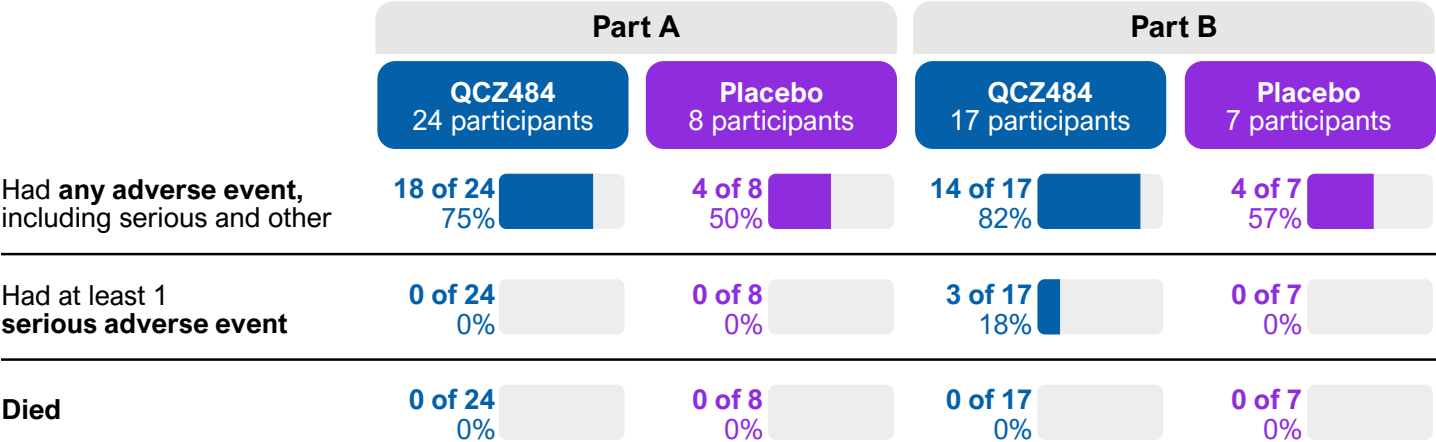
- No participants had a serious adverse event
- No participants died

Part B: 18 out of 24 participants with high blood pressure had adverse events, including serious and other adverse events.

- 3 participants had serious adverse events
- No participants died

The researchers concluded there were no safety concerns for **QCZ484** in this trial.

How many participants had adverse events?



What serious adverse events did the participants have?

In **Part A**, no healthy participants had serious adverse events.

In **Part B**, 3 participants with high blood pressure who received **QCZ484** had a total of 3 serious adverse events:

- **Not enough blood flow to the brain for a short time, or mini-stroke** | Transient ischemic attack
- **Panic attack**
- **Kidney stones in the tube that connects the kidneys to the bladder** | Ureterolithiasis

What other (not including serious) adverse events did the participants have?

In **Part A**, 22 healthy participants had adverse events. In **Part B**, 18 participants with high blood pressure had adverse events.

The table below shows the most common adverse events that happened in 3 or more participants in either **Part A** or **Part B**. Additional adverse events happened in fewer participants.

	Part A		Part B	
	QCZ484 24 participants	Placebo 8 participants	QCZ484 17 participants	Placebo 7 participants
Headache	3 of 24 13%	2 of 8 25%	4 of 17 24%	1 of 7 14%
Infection in the nose, throat, and airways Upper respiratory tract infection	2 of 24 8%	1 of 8 13%	6 of 17 35%	1 of 7 14%
COVID-19	1 of 24 4%	2 of 8 25%	2 of 17 12%	0 of 7 0%
High blood pressure that got worse Hypertension	0 of 24 0%	0 of 8 0%	3 of 17 18%	0 of 7 0%
Pain where the injection was given Injection site pain	3 of 24 13%	0 of 8 0%	0 of 17 0%	0 of 7 0%

What was learned from this trial?

Researchers learned about the safety and effects of different doses of **QCZ484** in healthy people and people with **mild hypertension**, also called high blood pressure.



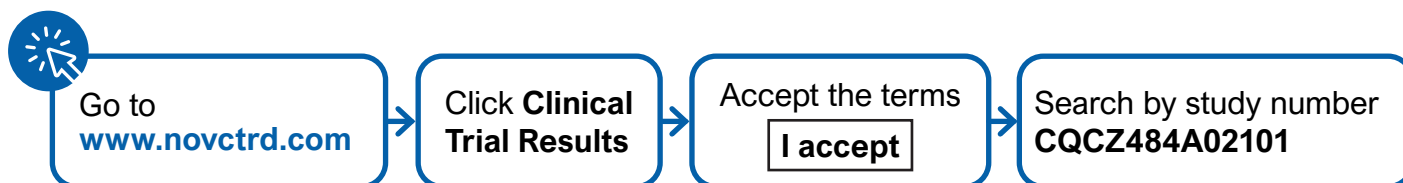
The researchers concluded there were no safety concerns for **QCZ484** in this trial.

When this summary was written, Novartis had plans for future trials of **QCZ484** in people with high blood pressure.

Where can I learn more about this trial?

To learn more about the results and adverse events in this trial, read the scientific summary of the results. It is available on the Novartis Clinical Trial Results website www.novctrd.com

Follow these steps to find the scientific summary:



For more information about this trial, go to this website:

- clinicaltrials.gov – search using the number **NCT06905327**

Other trials of **QCZ484** may appear on the public website above. When there, search for **QCZ484** or **BW-00163**.

Full clinical trial title: A Phase I, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Subcutaneously Administered QCZ484 in Healthy Subjects and Subjects with Mild Hypertension



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