

# A clinical trial to learn more about the heart safety of trial drug brolucizumab for people with wet age-related macular degeneration



## Thank you!

**Thank you to the participants** who took part in the clinical trial for the drug **brolucizumab**. All of the participants helped the researchers learn more about how safe brolucizumab is to take.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. An independent organization prepared this summary of the trial results.

We hope this helps the participants understand their important role in medical research.



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

## Trial information

**Trial number:** CRTH258A2309

**Drug studied:** brolucizumab  
(BROE-lue-SIZ-ue-mab)

**Sponsor:** Novartis

You can find **more information** about this trial by going to the website listed on **page 9** of this summary.

## This trial at a glance



### What was the purpose of this trial?

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This trial was designed to learn more about the safety of the trial drug brolucizumab, also called RTH258. Brolucizumab is designed to treat a type of age-related macular degeneration (AMD) called wet AMD. This clinical trial focused on safety for the heart.

### This trial was designed to answer these questions:

- Did brolucizumab have an effect on the participants' heart activity?
- What medical problems did the participants have during the trial? Keeping track of the medical problems helped to learn more about the safety of brolucizumab.



### Who was in this trial?

[Read more on page 3](#)

14 men and women completed this clinical trial. Every participant in this trial had wet AMD in at least one eye.



### What treatment did the participants receive?

[Read more on page 3](#)

All participants received one dose of brolucizumab as an injection (shot) in the eye.



### What were the main results of this trial?

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The clinical trial team found that brolucizumab had no meaningful effect on the participants' heart activity. They found no safety concerns during this trial.

## What was the purpose of this clinical trial?

This trial was designed to learn more about the safety of the trial drug **brolocizumab**, also called RTH258. This trial focused on safety for the heart.

Brolocizumab is designed to treat a type of age-related macular degeneration (AMD) called **wet AMD**. In wet AMD, abnormal blood vessels leak blood and fluid in the back of the eye. This can cause vision problems and vision loss, usually in people over the age of 65.

Before a drug can be approved for patients to take, researchers do many clinical trials to find out how safe it is and how it works.

**This trial was designed to answer these questions:**

- Did brolocizumab have an effect on the participants' heart activity?
- What medical problems did the participants have during the trial?

## Who was in this trial?

14 participants completed the trial – 8 women and 6 men.

Everyone was 64 to 87 years old. Their average age was 76.

Every participant in this trial had wet AMD in at least one eye.

This trial took place in the United States, including Puerto Rico.



For more information about who could and could not be in this trial, and the participants in this trial, visit [novctrd.com](https://novctrd.com). Use trial number **CRTH258A2309** to find the scientific summary.

## What treatment did participants receive?

All participants received one dose of brolocizumab, 6 mg (milligram) as an injection in the eye.

All participants and trial staff knew what treatment each participant received.

# What happened during this trial?

The trial began in June 2019 and ended in July 2019. 14 participants began and completed this trial.

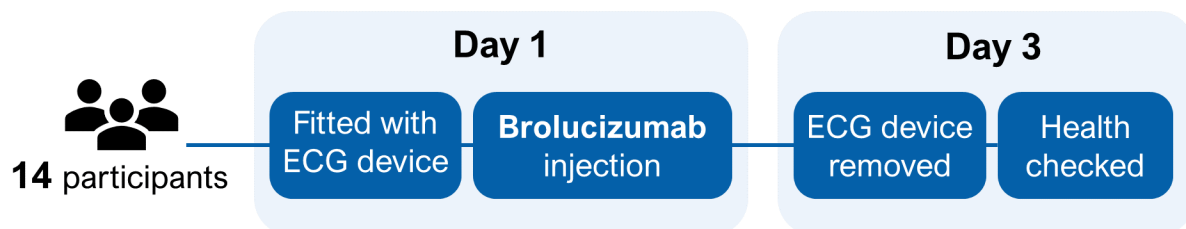
## Here's what happened during this clinical trial:

### Before treatment

- The trial doctors checked each participant's health and eyes to make sure they could be in this clinical trial
- The trial doctors made sure the participants stopped taking certain medicines

### During treatment

- 1 hour before injection, the trial staff fitted each participant with a wearable ECG device to measure their heart activity for 2 days
- 2 days after injection, the trial staff removed the device and checked each participant's health



### After treatment

- On the 8th and 31st days after treatment, the trial staff checked each participant's health by phone

# What were the main results of this trial?



This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other treatment is safe and works well. Other trials may provide new information or different results. Always talk to a doctor before making any changes to your health care.

## Did brolucizumab have an effect on the participants' heart activity?



The clinical trial team concluded that brolucizumab had no meaningful effect on the participants' heart activity.

To find this out, the clinical trial team measured the participants' heart activity using an electrocardiogram, also called an ECG.

An ECG measures the electrical signals that the heart makes each time it beats. These electrical signals cause the heart to squeeze and pump blood. The ECG shows the timing of the electrical signals as they travel through the heart.

The electrical signals form a pattern on the ECG that can show how well the heart is working. If this pattern changes, it means the heart may not be working correctly.

To find out if brolucizumab had an effect on heart activity, the clinical trial team looked at measures from a participant's ECG:

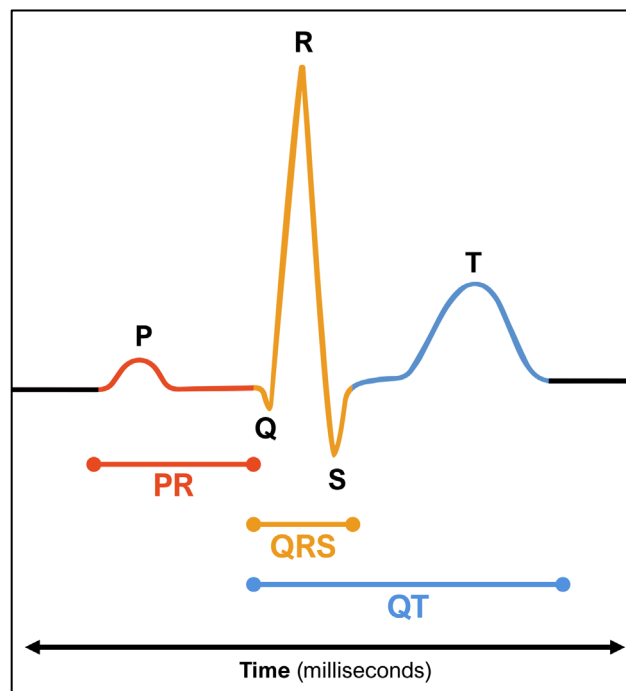
- **PR**: Shows activity of electrical signals through the upper part of the heart
- **QRS**: Shows activity of electrical signals through the lower part of the heart
- **QT**: Shows when the lower part of the heart resets to prepare for the next heartbeat
- **Heart rate**: How many times the heart beats in one minute
- **QTcF**: the QT measure adjusted for heart rate.

The clinical trial team calculated QTcF using QT and heart rate.

Before a participant received brolucizumab, trial staff fitted them with a small, wearable ECG device to measure their heart activity for 2 days after the injection.

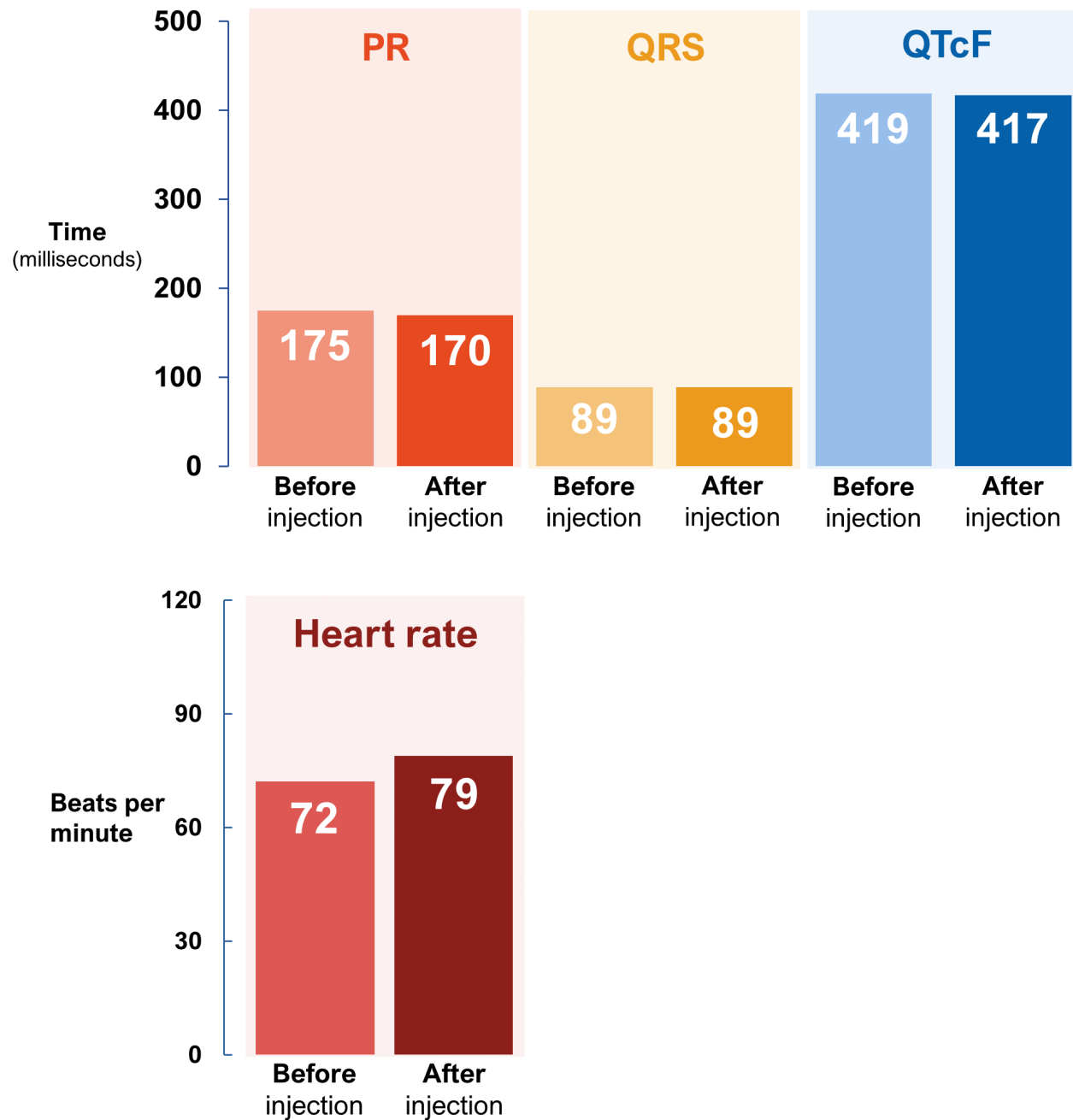
The clinical trial team compared the averages of the participants' heart activity before receiving the brolucizumab injection and 22 hours after. This is when brolucizumab usually reaches its highest level in the blood after injection.

### ECG measures for one heartbeat



On average, the participants' ECG measures after injection were within accepted ranges. The team found no meaningful differences in the participants' heart activity. The tables below show the participants' heart activity before and after injection.

**Average of the participants' heart activity before and 22 hours after brolucizumab injection**



## What medical problems did the participants have during the trial?

Medical problems that happen during clinical trials are called “adverse events”. An **adverse event** is any unwanted sign or symptom that participants have during a trial. An adverse event is considered “**serious**” when it is life-threatening, causes lasting problems, or the participant needs hospital care.



**Adverse events may or may not be caused by treatments in the trial.**

Many trials are needed to know if a drug or treatment causes an adverse event. Trial doctors keep track of all adverse events that happen in trials, even if they do not think the adverse events might be related to the trial treatments.



The clinical trial team found no safety concerns during the trial.

The trial doctors looked for any adverse events when they checked the participants’ health. The participants also reported adverse events.

### Participants who had adverse events

	<b>Brolucizumab 6 mg dose</b> (out of 14 participants)
<b>Participants who had:</b>	
Adverse events	7% (1)
Serious adverse events	0% (0)
Left this trial due to adverse events	0% (0)

## What serious adverse events did participants have?

During this clinical trial, no participants reported serious adverse events and no participants died.

## What types of adverse events did participants have?

1 of the 14 participants reported an adverse event that was not serious. It was:

- **An increase in eye pressure** (intraocular pressure increased) that lasted for one minute after the brolucizumab injection



For more information about the adverse events reported by the participants in this clinical trial, visit [novctrd.com](https://novctrd.com). Use clinical trial number **CRTH258A2309** to find the scientific summary.

## What was learned from this trial?

This trial helped learn more about the safety of brolucizumab on heart activity for people with wet AMD.

At the time of this trial, brolucizumab was not an approved drug. Because of what was learned from this and other clinical trials, brolucizumab was approved to treat wet AMD in Australia, Canada, Japan, Switzerland, and the United States at the time this summary was written.



The results presented here are for one clinical trial. One trial cannot give a complete picture of the benefits and risks of a trial drug. The results of many trials are needed to find out which treatments can be used for people with wet AMD. This summary shows only the main results from this trial. Other trials may provide new information or different results.

## Where can I learn more about this and future clinical trials?



This is a summary of the results for one trial.

You can find detailed results and more information about this trial on the Novartis Clinical Trial Results website:

1. Visit [novctrd.com](https://novctrd.com)
2. Click on “Clinical trial results and trial summary for patients” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Select “Search by study number” on the bottom left of the page
5. Type “**CRTH258A2309**” in the search box and click search

If you would like to view the website in a language other than English, you can click the “Google Translate” button on the top right of the page.





If you were in this trial and have questions about the results, please speak with the doctor or staff where you took part in this trial.

This clinical trial was registered on the following website:

- ClinicalTrials.gov – <https://clinicaltrials.gov/>

To find this trial, type CRTH258A2309 in the **Other terms** search box

**Full trial title:**

A single-arm, open-label, multicenter, phase IIIb study to collect safety and electrocardiogram data on brolocizumab 6 mg intravitreal treatment in patients with neovascular age-related macular degeneration

If more clinical trials are planned, they will appear on the public website listed on above or at [www.novartisclinicaltrials.com](http://www.novartisclinicaltrials.com). When there, search for 'brolocizumab' or 'RTH258'.

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## Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The participants made this clinical trial possible and helped researchers answer important health questions and learn about a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.

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