Summary of Clinical Trial Results

Clinical trial to determine the safety and convenience of brolucizumab administered in pre-filled syringes to participants with wet age-related macular degeneration

Protocol number: CRTH258A2308

Thank you!

Novartis, the sponsor of this clinical trial, would like to thank you for taking part in this trial for the medication RTH258, also known as brolucizumab. You have helped researchers learn more about the safety of brolucizumab when administered to people with vision loss due to wet age-related macular degeneration.

As a clinical trial participant, you belong to a large community of people around the world. Your invaluable contribution to medicine and healthcare is greatly appreciated.

This summary only shows the results of a single clinical trial. Other clinical trials may have different results. Researchers and health authorities, such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe, look at the results of many clinical trials to understand which medications work and whether they are safe. Many people in many clinical trials around the world are needed to advance medical science and healthcare. If you have any questions about these trial results, talk to the doctor or staff of your trial site.

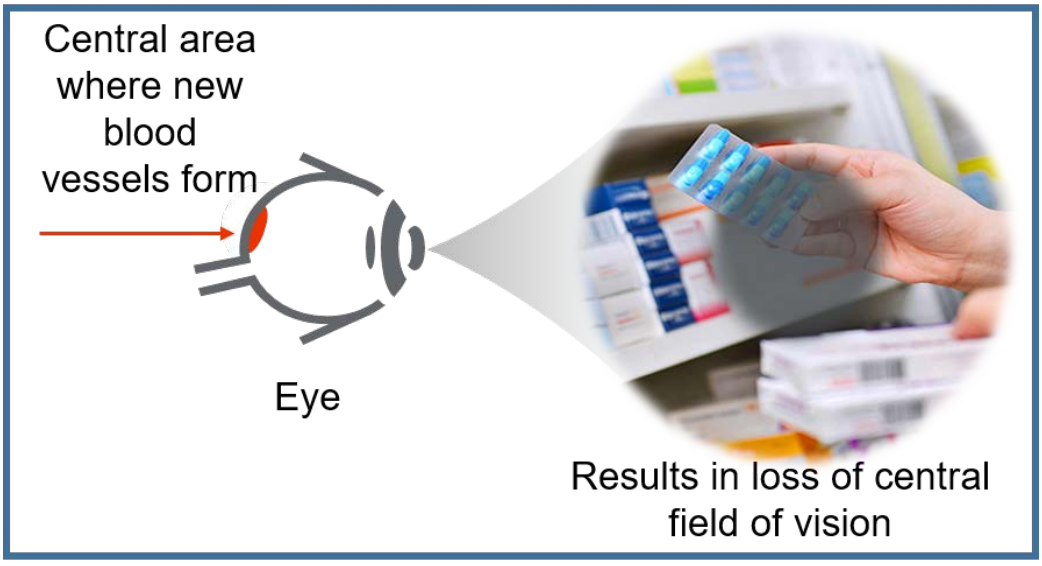
How long did this trial last?

The trial started in May 2019 and ended in July 2019. The total duration of the trial, from the enrollment of the first participant until the last participant completed the trial, was approximately one and a half months. Each participant could be in this trial for approximately 31 days.

Researchers completed this trial as planned. When the trial ended, researchers gathered information about the trial treatments (RTH258, also known as brolucizumab) and created a report of the trial results. This summary is based on that report.

Why was the research needed?

Researchers looked for a better way to treat an eye disorder called wet age-related macular degeneration. Normally, this condition may cloud the central part of vision as a person ages. Sight is lost due to the formation of new blood vessels inside the eye. The new blood vessels that form are very delicate and leak blood and fluid into the eye. This causes swelling and slow vision loss.



Brolucizumab is the drug studied in this trial for the treatment of wet age-related macular degeneration. In previous trials, brolucizumab was available as a solution stored in a bottle. To administer it to participants, researchers used a syringe with a

needle to draw the solution from the bottle and then switched to another needle to administer the injection into the eye. In this trial, researchers changed brolucizumab administration method to a pre-filled syringe (called “pre-fill”) with the solution. This made it more convenient for researchers to administer the trial drug, without having to withdraw liquid from the vial.

The main goal of this trial was to learn more about the safety of brolucizumab when administered to participants using a pre-filled **syringe**.

Trial drug

Brolucizumab (RTH258) 6 mg: trial drug being studied for the treatment of wet age-related macular degeneration. This drug was given to participants as an injection into the eye through a pre-filled syringe.

Throughout the trial, participants were not allowed to take any other medications.

Purpose of the trial

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

- Did brolucizumab 6 mg cause any medical problems when administered as an injection in the eye through a pre-filled syringe?

Who participated in this trial?

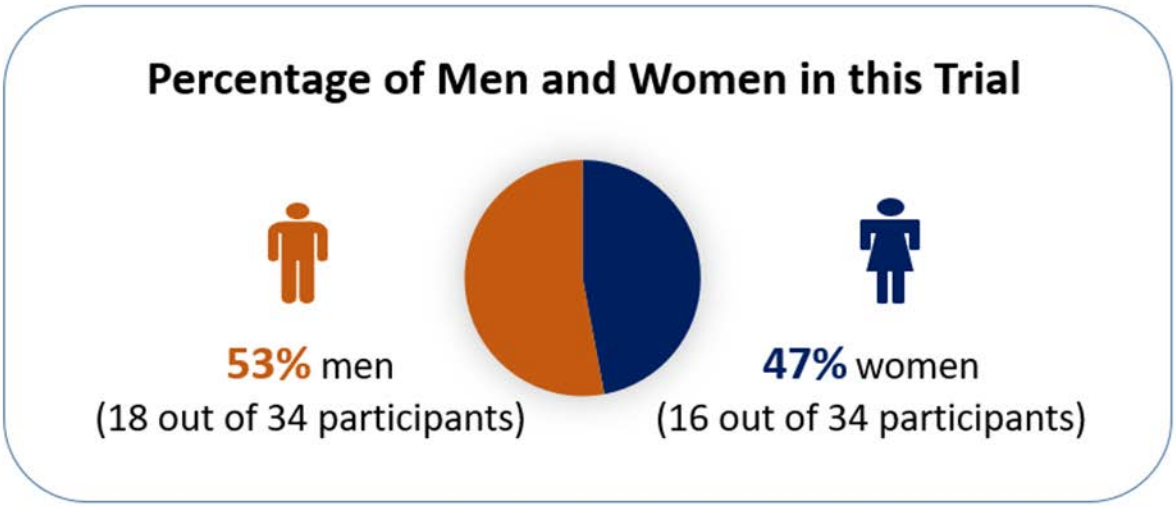
Participants were allowed to take part in this trial if they:

- were 50 years or older at the beginning of the trial;
- had been diagnosed with age-related wet macular degeneration and needed treatment as an injection into the eye;
- had not received any other treatment in the form of an injection into the eye until 1 month prior to the beginning of the trial or had not recently undergone eye surgery;

- had not received corticosteroid treatment in the study eye until 3 months prior to the beginning of the trial;
- had no other serious eye conditions, high blood pressure, or other serious conditions.

A total of 34 participants participated in this trial at 3 sites in the United States.

The average age of participants was 77 years old. The age of participants ranged from 51 to 90 years old.



What type of trial was this?

This was an open-label trial. This means that both researchers and participants knew that each participant received a single 6-mg injection of brolucizumab into the eye through a pre-filled syringe.

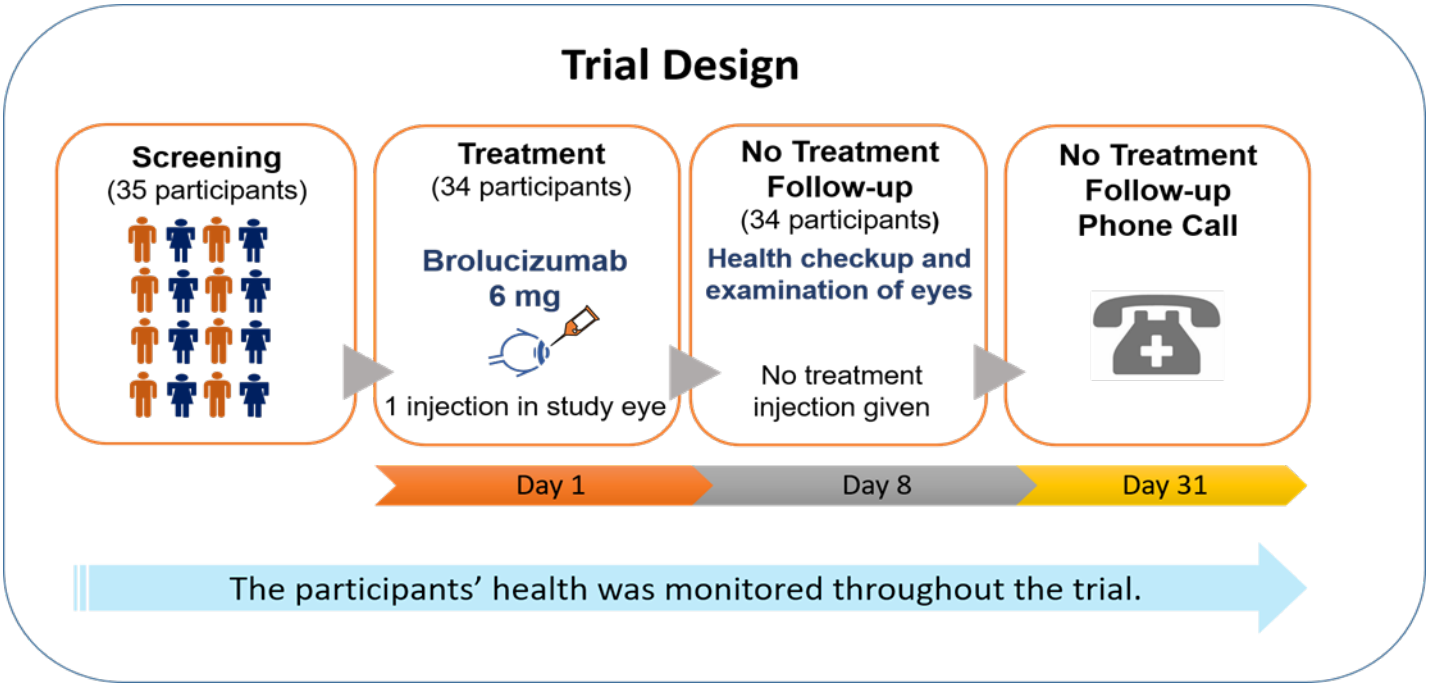
What happened during this trial?

Before any treatment was administered, participants went through a screening period to make sure they were in good health and met the criteria for participating in this trial.

Eligible participants were administered 1 6-mg injection of brolucizumab into the eye on treatment day 1. The eye that received the injection was called the “study eye”.

Participants returned to the study site on day 8 and had their eyes examined for any medical problems.

Participants' health was monitored continuously throughout the trial. For participants who reported medical problems on day 8, a follow-up call was scheduled for day 31.



What was the result of this trial?

This is a summary of the average results for all participants. It does not show the results of each individual participant. The results of each individual participant could be different from the results of the total group of participants. A detailed presentation of the results can be found on the websites listed at the end of this summary.

Did brolucizumab 6 mg cause any medical problems when administered as an injection in the eye through a pre-filled syringe?

No medical problems or adverse events were reported in participants who received 6 mg of brolucizumab as a single injection through a pre-filled syringe. No deaths were reported during this trial. No participants were withdrawn from this trial due to adverse events.

Medical problems that happen in clinical trials are called “adverse events”.

A lot of research is needed to know whether a medication causes an adverse event. During a trial, all adverse events are recorded, whether or not they are thought to be caused by the trial medication. When new medications are studied, researchers keep track of all the adverse events that participants have.

An adverse event is an unwanted sign, symptom, or disease 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. These problems may or may not be caused by the trial drug.

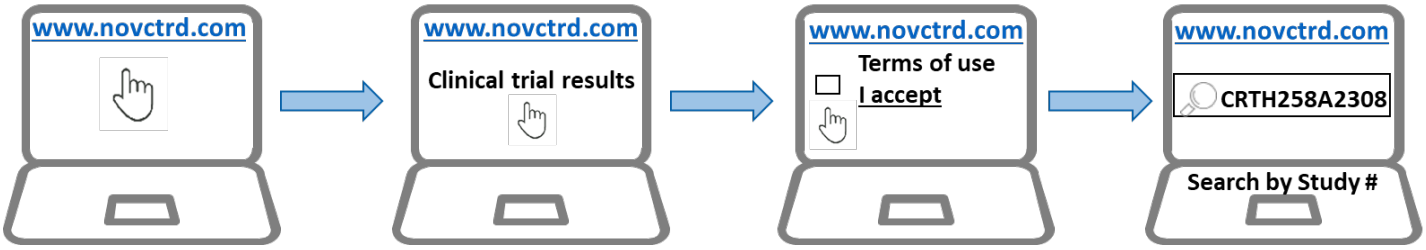
How was this trial useful?

This trial helped researchers learn about the safety and convenience of a single 6-mg injection of brolucizumab when administered through pre-filled syringes in participants with wet age-related macular degeneration. The results of this trial helped show that one 6 mg injection of brolucizumab, when administered through pre-filled syringes, was safe and can be used in other clinical trials for people with wet age-related macular degeneration.

Remember that this summary shows only the results of a single clinical trial. Other clinical trials may have different results. Researchers and health authorities analyze the results of many clinical trials to understand which medications work, and whether they are safe. Many people in many clinical trials around the world are needed to advance medical science and healthcare. If you have any questions about these trial results, talk to the doctor or staff of your trial site.

Where can I find out more about this trial?

You can find more information about the results and adverse events of this trial in the scientific summary of results available on the Novartis Clinical Trial Results website (www.novctrd.com).



You can find more information about this trial on the following website:

- www.clinicaltrials.gov Use the national clinical trial (NCT) identifier NCT03930641 in the search field.

Full clinical trial title: An Open-Label, Single-Arm, Multicenter, Phase IIIb Study in Patients with Neovascular Age-Related Macular Degeneration to Evaluate the Safety of Brolucizumab 6 mg in Prefilled Syringe

Thank you

Thank you for participating in this trial. As a clinical trial participant, you belong to a large community of people around the world. You have helped researchers answer important health questions and assess new medical treatments.

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