Clinical Trial Results Summary

A clinical trial to find out if UNR844-Cl is safe and can improve presbyopia, the inability to see objects up close

Protocol number: CUNR844A2203

Thank You!

Novartis, the sponsor of this clinical trial, would like to thank you for taking part in this trial for the drug UNR844-Cl. You helped researchers to find out if UNR844-Cl is safe and can improve presbyopia, the inability to see objects up close.

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 findings. 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 drugs work and if they are safe. It takes many people in multiple clinical trials around the world to advance medical science and healthcare. If you have any questions about these trial results, please talk to the doctor or staff at your trial site.

How long was this trial?

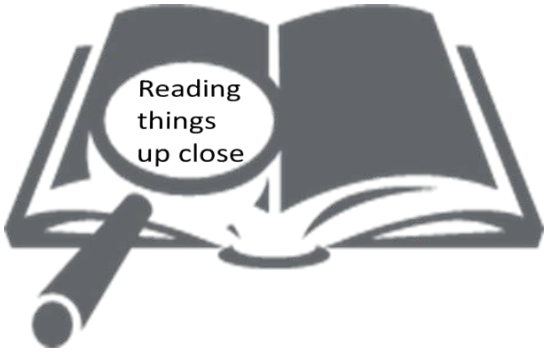
This trial was designed so that an individual participant could take part for 3 months. The trial started in April 2019 and ended in December 2019. The entire duration, from enrolling the first participant to the last participant completing the trial, was 8 months.

Not all participants joined the trial at the same time but each participant was in the trial for the same duration. Therefore, some participants entered and finished the trial earlier than others.

The researchers completed this trial as planned. When the trial ended, the researchers collected information on the trial treatments (UNR844-Cl and placebo) and created a report of the trial results. This summary is based on that report.

Why was the research needed?

Researchers were looking for a better way to treat presbyopia. Presbyopia is a condition in which people have trouble reading and seeing things up close, as they get older. Presbyopia is more likely to develop in people aged 40 years or above. There is currently no other drug available for presbyopia and the condition is usually managed by use of reading glasses.



In this trial, researchers were studying the safety and effects of UNR844-Cl compared to placebo in participants with presbyopia. This was done by measuring the eye exam scores of participants with presbyopia.

Trial drugs

The drugs given in this trial were:

UNR844-Cl

An investigational drug, given as an eye-drop, that is not yet approved by any regulatory agency being studied for the treatment of presbyopia. It is thought to act by preventing the hardening of lens proteins. When these proteins harden, they prevent the lens from changing its shape, causing a reduction in the ability to focus on near objects.

Placebo

It looks like the trial drug, but did not have any medicine in it. Using a placebo helps researchers better understand the effect of a trial drug by making sure that the changes were not happening by chance.

Trial purpose

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

Did treatment with UNR844-Cl for 3 months improve eye exam scores of participants with presbyopia aged 45 to 55 years compared to placebo?

The other question researchers wanted to answer in this trial was:

- Did the participants have any medical problems during the trial?

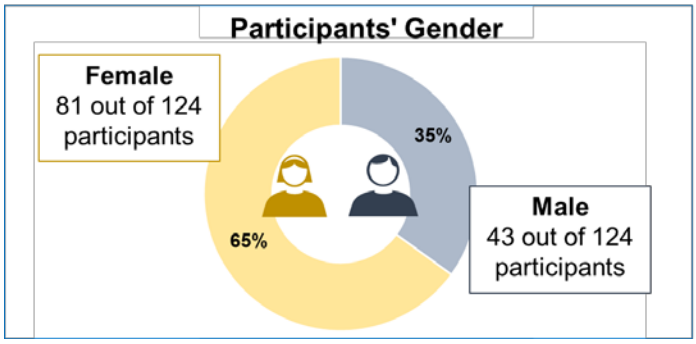
Who was in this trial?

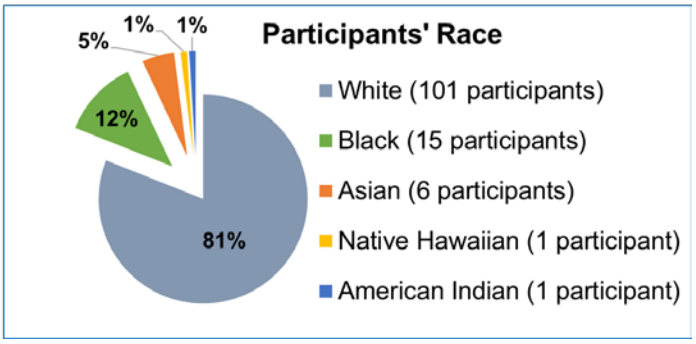
The participants could take part in this trial if they:

- were aged 45 to 65 years.
- had eye exam score of less than 70 letters (20/40 vision) for each eye and when using both eyes, without the help of reading glasses or contact lenses.
- needed reading glasses or contact lenses at a strength of at least +1.00 Diopter (D) to achieve an eye exam score of at least 85 letters (20/20 vision). “Diopters” is the unit used to measure the power of lens that the eye requires for better vision.
- did not have severe difficulty seeing things clearly that are close to or far from the eyes.
- did not have any significant medical or clinical conditions affecting their vision, eyes or general health.

A total of 124 participants in the United States (US) participated in this trial.

The average age of participants was 54 years. Participants’ age ranged from 45 to 65 years. The majority of participants 65% (81 out of 124) were female. 81% (101 out of 124) of the participants were white, as shown below.





What kind of trial was this?

This was a double-blind trial. This means that none of the participants, trial doctors, or trial staff knew what treatment participants were receiving. Some trials are done this way because knowing what treatment each patient is getting can affect the results of the trial. Doing a trial this way helps to make sure that the results are looked at with fairness towards all treatments.

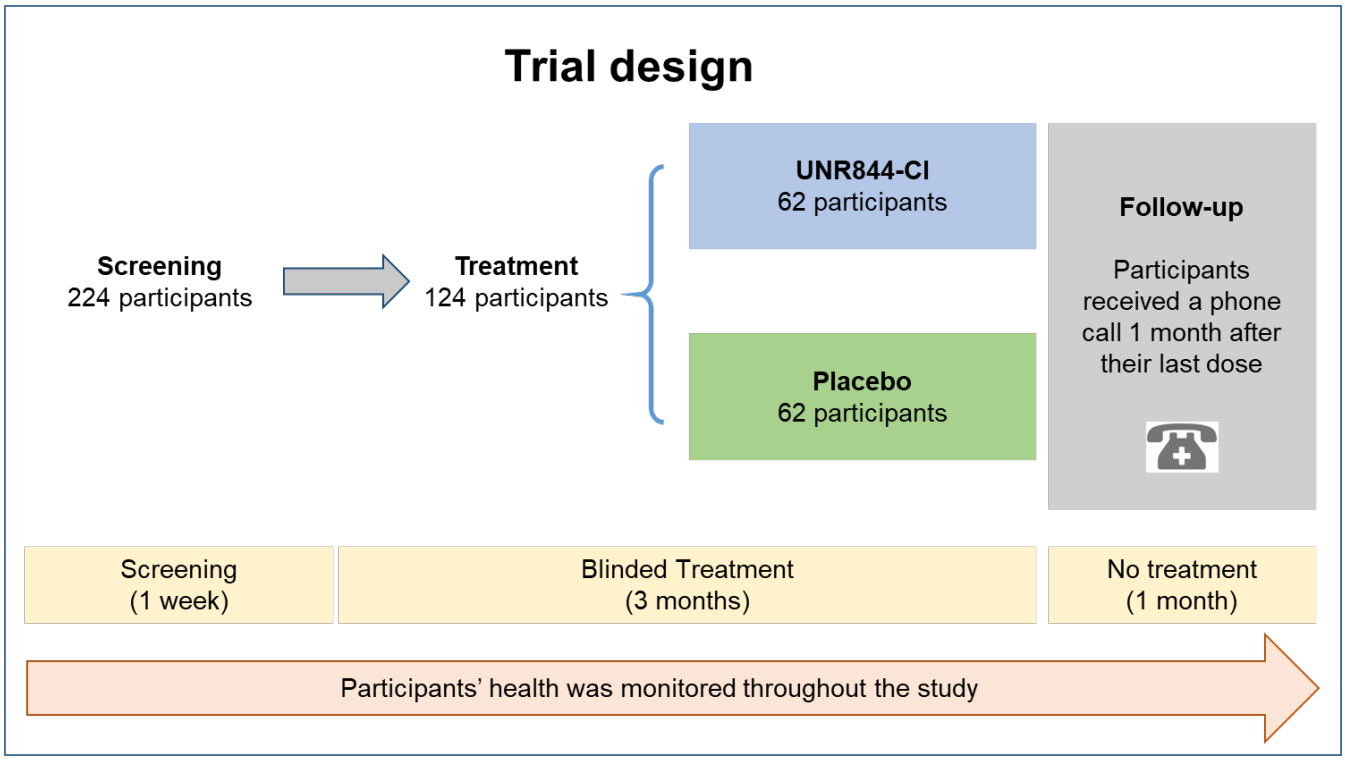
What happened during this trial?

Participants went through a screening to confirm that they could take part in the trial. At the start of the trial, the researchers randomly assigned the participants to receive:

- **UNR844-CI:** as an eye drop, 1 drop in each eye 2 times a day
- **Placebo:** as an eye drop, 1 drop in each eye 2 times a day.

This process is called randomization. Participants had an “equal” or 50% chance (like flipping a coin) of receiving either UNR844-CI or placebo.

Participants’ vision was tested by the trial doctor at the start of the trial and after 3 months of treatment with UNR844-CI or placebo, using a computerized eye exam system. Participants looked at an electronic chart and let the trial doctor know the smallest letters that could be read.

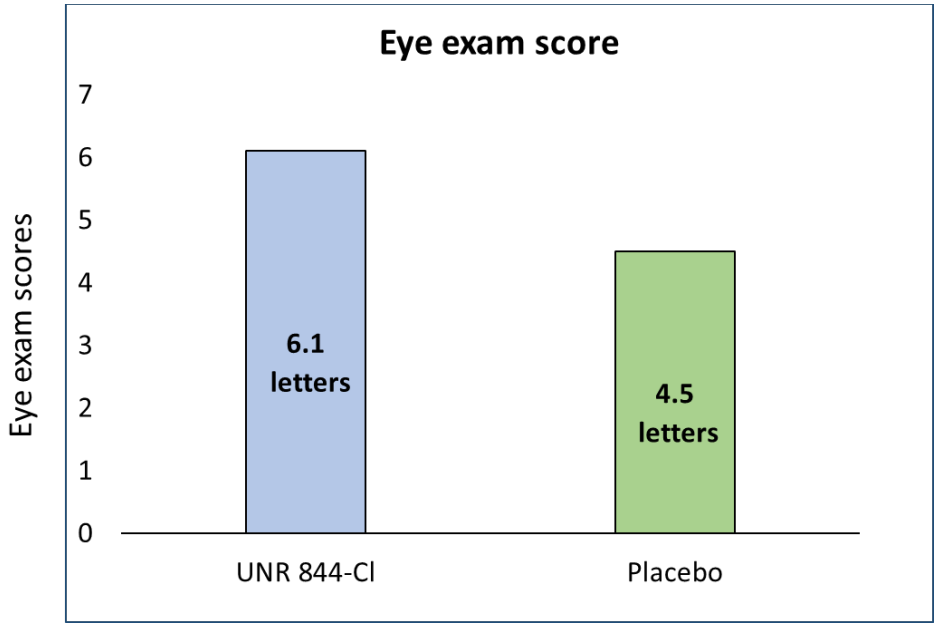


What were the key results of this trial?

This is a summary of the average results for all participants in different treatment groups. It does not show the results of each individual participant. Results of individual participants 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 treatment with UNR844-Cl for 3 months improve eye exam scores of participants with presbyopia aged 45 to 55 years compared to placebo?

The average eye exam scores of participants given UNR844-Cl improved by **6.1** letters. For the participants who were given placebo, the scores improved by **4.5** letters. However, the difference in the eye exam scores after 3 months of taking UNR844-Cl was not large enough to be considered better than placebo, and may have been due to chance.



Did the participants have any medical problems during the trial?

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

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

This section is a summary of the adverse events that happened during this trial. The websites listed at the end of this summary may have more information about all the adverse events that happened in this trial.

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 many participants had adverse events?

Not all participants in this trial had adverse events. 19 out of 124 participants (15%) had 1 or more adverse events.

Number (Percentage) of Participants With Adverse Events

	UNR844-CI (Out of 62 participants)	Placebo (Out of 62 participants)
At least 1 adverse event	14 (23%)	5 (8%)

None of the participants in the trial had a serious adverse event. No participant died during this trial. None of the participants stopped the drug early because of an adverse event.

What were the most common non-serious adverse events?

The most common non-serious adverse events that happened in at least 2 participants in either the UNR844-CI or the placebo groups are presented below.

Number (Percentage) of Participants With Non-Serious Adverse Events

	UNR844-CI (Out of 62 participants)	Placebo (Out of 62 participants)
Change in sense of taste	3 (5%)	0
Headache	2 (3%)	0

Please refer to websites listed at the end of this summary for more details.

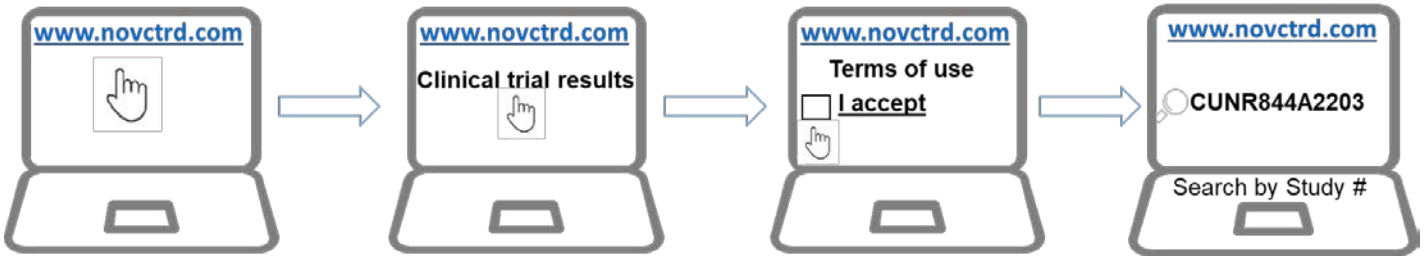
How was this trial useful?

This trial helped researchers learn how well UNR844-CI works and if it is safe to use in people with presbyopia. The results of this trial showed that the difference in average letters read after 3 months of taking UNR844-CI was not better than placebo. The researchers may perform more clinical trials to further learn about the effects and safety of UNR844-CI in people with presbyopia.

Please remember, this summary only shows the results of a single clinical trial. Other clinical trials may have different results. If you have any questions about these trial results, please talk to the doctor or staff at your trial site.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the 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 NCT identifier NCT03809611 in the search field.

Full clinical trial title: A 3-month, randomized, placebo-controlled, doublemasked, multi-center study to evaluate the safety and efficacy of topical ocular UNR844-Cl in subjects with presbyopia.

Thank you

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

NOVARTIS

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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