NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of SAF312 in people with chronic eye pain after eye surgery

Thank you!

Thank you to the participants who took part in the clinical trial for **chronic eye pain after eye surgery**. Every participant helped the researchers learn more about the trial drug **SAF312**, also called libvatrep.

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

Trial information

Trial number: CSAF312B12201

Novartis drug studied: SAF312, also known as libvatrep

Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the 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 more about the effects of **SAF312** in people with chronic (long-lasting) eye pain after eye surgery.

Chronic eye pain after eye surgery is pain in the eye that lasts at least 4 months after eye surgery, such as LASIK or cataract surgery. Chronic eye pain can feel like:

- Burning or stinging
- Stabbing
- Pressure
- Something in the eye

SAF312, also known as libvatrep, is a trial drug designed to be used as eye drops to lessen eye pain.

Trial drug
SAF312 also called libvatrep

Pronounced as
lib-va-trep

The trial purpose was to answer these main questions:

- Was participants' eye pain less severe after using SAF312 for 3 months?
- What adverse events did the participants have?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.

How long was this trial?

The trial began in April 2021 and ended in June 2023. The participants were in the trial for about 6 months.

Who was in this trial?

150 participants with chronic eye pain after eye surgery received treatment in this trial – 41 men and 109 women.

Participants' ages ranged from 27 to 85 years. Their average age was 59 years.

The number of participants by race is shown below.

Race

23 Asian	15 Black or African American
1 Native Hawaiian or Pacific Islander	110 White
1 More than one race	

The participants in this trial had at least one of these **eye surgeries** in both eyes:

- **Cataract surgery**, including clear lensectomy
- **LASIK**, which stands for laser-assisted in situ keratomileusis
- **PRK**, which stands for photorefractive keratectomy
- **RK**, which stands for radial keratotomy
- **LASEK**, which stands for laser-assisted sub-epithelial keratectomy
- **SMILE**, which stands for small incision lenticule extraction

The participants could take part in this trial if they:

- Had not used nerve growth factor (NGF) eye drops for at least 2 weeks – NGF eye drops help cells in the eye to heal
- Did not have other eye conditions, such as an eye infection

150 participants from 3 countries received treatment. The map below shows the number of participants who took part in each country.

What treatments did the participants receive?

The treatments in this trial were:

SAF312, also known as libvatrep, which participants took as eye drops. This trial looked at 2 doses of **SAF312**:

- **15 milligrams per milliliter (mg/mL)** twice a day
- **5 mg/mL** twice a day

Placebo, which participants took as eye drops twice a day. Placebo does not have any trial drug in it. Using a placebo helps researchers better understand the effect of a trial drug.

The participants, trial doctors, and most of the 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 — 3 months

Trial doctors checked the participants' health and eye pain level to make sure they could be in this clinical trial.

During treatment — 3 months

150 participants received one of these treatments as eye drops twice a day:

15 mg/mL SAF312	50 participants
5 mg/mL SAF312	49 participants
Placebo	51 participants

Researchers checked the participants' eye pain level and general health throughout the trial.

After treatment — 30 days

Trial staff called participants one time about 4 days after their last trial visit during treatment to check their health.

The researchers kept track of all adverse events reported up to 30 days after the participants' last dose of trial treatment.

What were the main results of this trial?

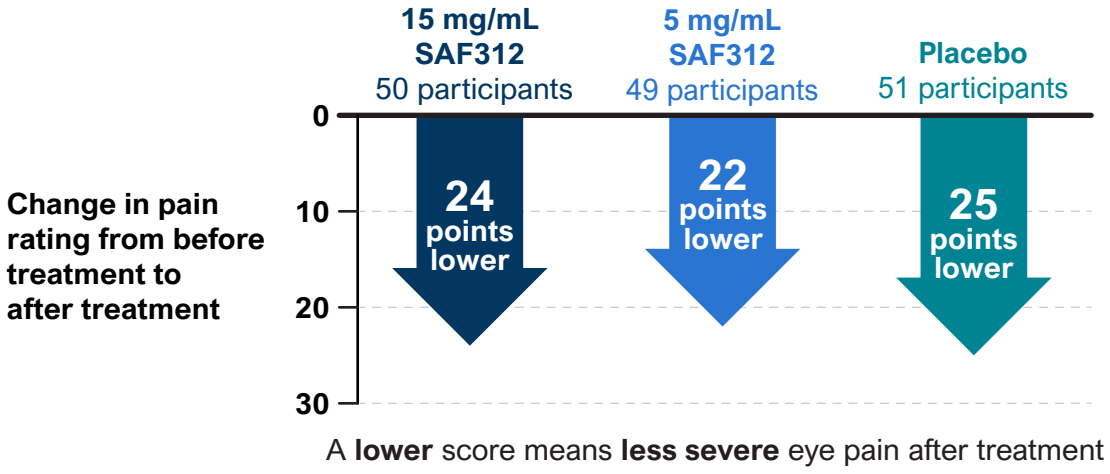
Was participants' eye pain less severe after using SAF312 for 3 months?

Overall, participants in all groups had about the same change in eye pain severity after 3 months of trial treatment. The researchers concluded that **SAF312** did not have a meaningful effect on the participants' eye pain.

Participants rated their eye pain severity every day for 3 months on a mobile device. Participants rated their pain using a scale of **0 (no pain)** to **100 (worst imaginable pain)**.

The researchers compared the average pain ratings each week of treatment to before treatment. The graph below shows the average change in pain ratings after 3 months of trial treatment.

Change in eye pain after 3 months of trial treatment



What were the other results of this trial?

Did participants have less eye pain after using SAF312 based on other measures?

Overall, compared to before trial treatment, participants in all groups had less eye pain after trial treatment based on their answers to questions about:

- Eye pain severity
- Eye pain frequency
- How eye pain affected their daily life

The researchers concluded that **SAF312** did not have a meaningful effect on these measures.

Did participants' eye health change after using SAF312?

Overall, none of the groups had changes in measures of eye health after trial treatment, including redness or discomfort in the eye, signs of inflammation (swelling), and dry eye. The researchers concluded that **SAF312** did not have a meaningful effect on eye health.

What adverse events did the participants have?

Trial doctors keep track of all **adverse events** that happen in trials, even if they think the adverse events are not related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of trial treatment until 30 days after the last dose of trial 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, the participant needs hospital care, or results in death

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

About a third of the participants (51 of 150) had adverse events. One participant had adverse events that were considered serious. No participants died. 3 participants left the trial due to an adverse event. The researchers concluded there were no safety concerns for **SAF312** in this trial.

How many participants had adverse events?

Participants who:	15 mg/mL SAF312 50 participants	5 mg/mL SAF312 49 participants	Placebo 51 participants
Had at least 1 **serious adverse event**	0 of 50 0%	0 of 49 0%	1 of 51 2%
Had at least 1 **other adverse event**	21 of 50 42%	12 of 49 24%	18 of 51 35%
Left the trial due to an adverse event	1 of 50 2%	1 of 49 2%	1 of 51 2%
Died during the trial	0 of 50 0%	0 of 49 0%	0 of 51 0%

What serious adverse events did the participants have?

One participant in the placebo group had a serious adverse event that was not in the eye:

- **Broken bone in the spine** (Spinal compression fracture)

No participants died.

What other adverse events did the participants have?

51 participants had other adverse events.

The table below shows the other **adverse events** that happened in **4 or more** of all participants.

	15 mg/mL SAF312 50 participants	5 mg/mL SAF312 49 participants	Placebo 51 participants
COVID-19	2 of 50 4%	1 of 49 2%	3 of 51 6%
Eye pain	3 of 50 6%	0 of 49 0%	2 of 51 4%
Dry eye	2 of 50 4%	2 of 49 4%	0 of 51 0%
Mucus coming from the eye Eye discharge	1 of 50 2%	2 of 49 4%	1 of 51 2%

What was learned from this trial?

This trial helped to learn more about the effects of **SAF312** in people with chronic eye pain after eye surgery.

The researchers concluded that:

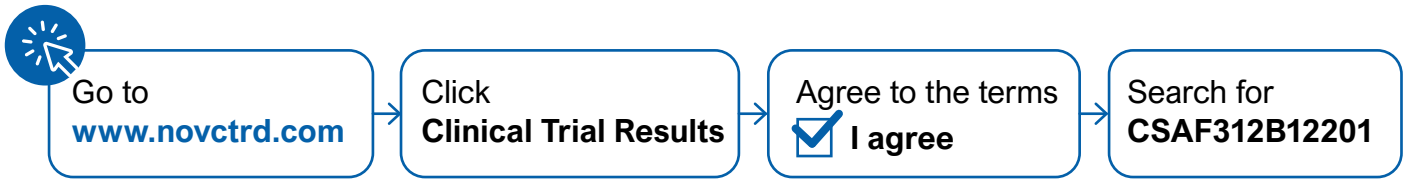
- **SAF312** did not have a meaningful effect on the participants' eye pain or eye health after 3 months of treatment
- There were no safety concerns for **SAF312** in this trial

When this summary was written, the sponsor had no plans for future trials of **SAF312** in people with chronic eye pain.

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**

Follow these steps to find the scientific summary:



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

- **clinicaltrials.gov** – search using the number **NCT04630158**

Other trials of **SAF312** may appear on the public website above. When there, search for **SAF312** or **libvatrep**.

Full clinical trial title: A 12-week parallel group, randomized, placebo-controlled, double-blinded, multi-center study to evaluate efficacy and safety of 2 concentrations of SAF312 eye drops (5 mg/ml and 15 mg/ml) used twice-daily in the treatment of post-operative corneal induced chronic pain (CICP) following Photorefractive Keratectomy (PRK) or Laser-assisted in Situ Keratomileusis (LASIK) surgeries

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

1-888-669-6682 (US) | +41-61-324 1111 (EU)

www.novartis.com/clinicaltrials