

The safety of LNA043 in Japanese people with osteoarthritis of the knee



Thank you!

Thank you for taking part in this clinical trial. Every participant helped the researchers learn more about **LNA043**. You helped advance science and medicine by being part of this trial.

What was the main purpose of this trial?

The main purpose of this trial was to learn about the safety of LNA043 in Japanese participants with osteoarthritis of the knee. To find this out, the clinical trial team compared the results from people who received LNA043 to those who received the placebo. This was the first trial to test LNA043 in Japanese people.



Osteoarthritis is caused by the wear and tear of the cartilage in a joint. Cartilage cushions the joint and allows it to move smoothly. The most common symptoms of osteoarthritis are stiffness, pain, swelling, and difficulty in moving the joint. It most commonly affects the joints in the knees, hands, hips, and spine.



LNA043 is a trial drug designed to help damaged cartilage heal. It acts like a protein in the body that encourages cartilage to grow.

Placebo – looks like the trial drug but has no trial drug in it.

The main question this trial was designed to answer:

- What medical problems did the participants have during this trial?
Keeping track of the medical problems helped researchers learn about the safety of LNA043.



Main results: Most of the participants had medical problems during this trial. A similar number of participants in each treatment group had medical problems. The most common medical problem was diarrhea. None of the medical problems were considered serious. The team found no safety concerns for LNA043.

How long was this trial?



The trial began in September 2020 and ended in December 2020. This trial was designed so that each participant could take part in the trial for about 2 months.

Who was in this trial?



12 participants were in this trial – 11 women and 1 man. The participants were 45 to 79 years old.

Every participant in this trial had osteoarthritis of the knee for at least 6 months before starting the trial. Participants in this trial did not have:

- a joint replacement in the knee that received the trial injection
- planned joint replacement for either knee during the trial
- surgery of the knee within 6 months of starting the trial
- certain alternative therapies for the knee within a month of starting the trial



This trial took place in Japan.

Visit novctrd.com for more information about:

- Who could and could not be in this trial
- The participants in this trial, such as their age and gender

Use trial number **CLNA043A11101** to find the scientific summary.

What trial treatments did the participants receive?

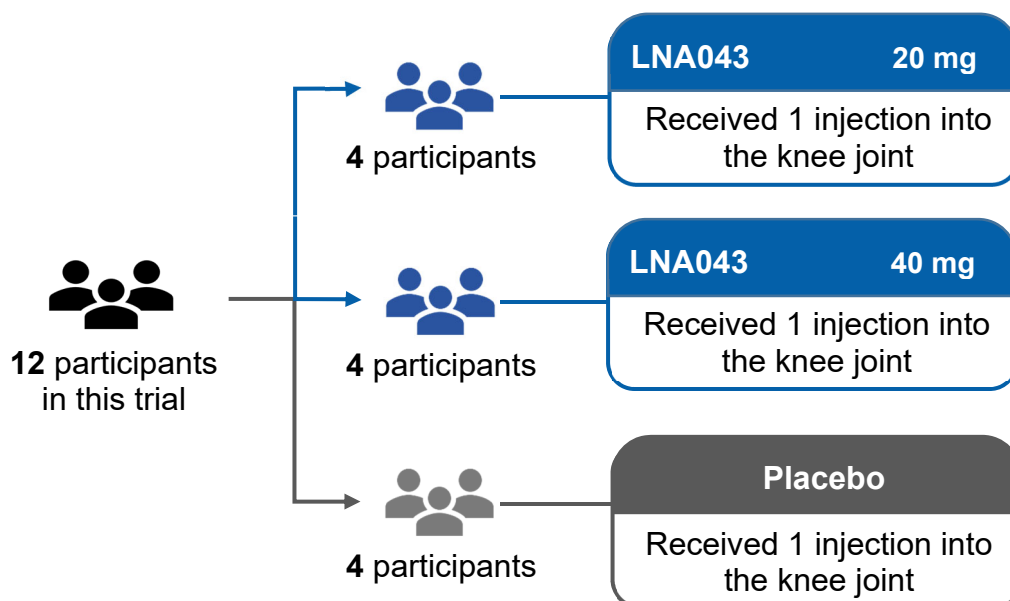


A computer program was used to randomly assign each participant to one of the following:

- **LNA043** – 20 milligrams (mg) or 40 mg, given as an injection into the knee joint one time during the trial.
- **Placebo** – looks like the trial drug but has no trial drug in it. It was also given as an injection into the knee joint one time during the trial. Using a placebo helps researchers better understand the actual effects of a trial drug.

Along with the trial treatment, the participants could take certain medicines as needed to manage the pain in the knee.

The graphic below shows the number of participants assigned to each trial treatment.



The participants and trial staff did not know what treatment each participant received during the trial. Some trials are done this way because knowing what treatment participants receive can influence the results. Not knowing what treatment participants receive during a trial helps make sure the results are looked at fairly.

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.

What medical problems did the participants have during this trial?

Medical problems that happen during trials are called “adverse events”. Trial doctors looked for any adverse events during the visits to the trial site. The participants also reported adverse events.

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 think the adverse events are not related to the trial treatments.

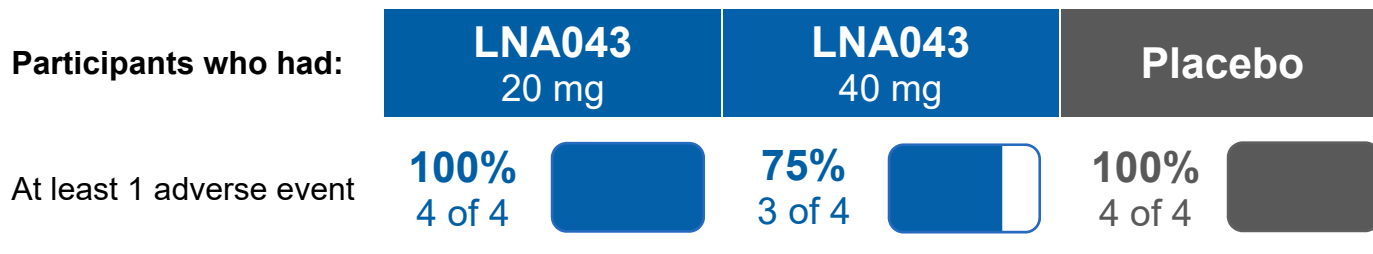
An adverse event is:

- any **unwanted sign or symptom** that participants may have during a trial.
- considered “**serious**” when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death.

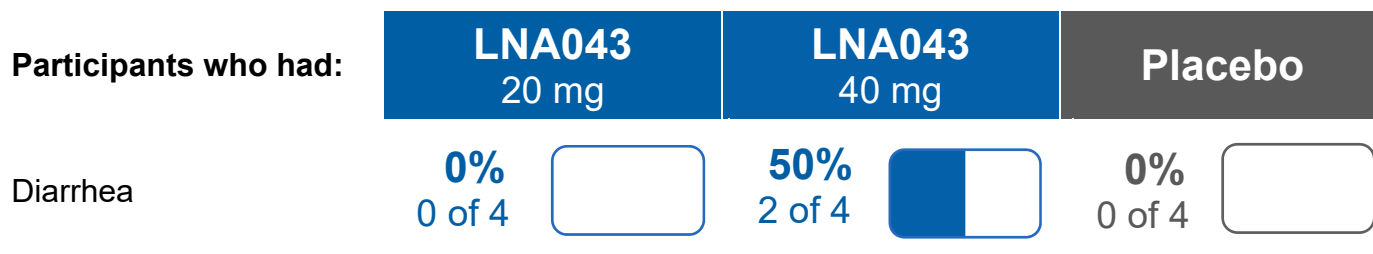
Adverse events **may or may not be caused** by treatments in the trial.



Most of the participants had adverse events during this trial. A similar number of participants in each treatment group had adverse events. The most common adverse event was diarrhea. None of the adverse events were considered serious. No safety concerns were found in this trial.



The adverse event that happened in **2 or more participants** was:



Other adverse events happened in no more than 1 participant in each group. No serious adverse events were reported, including deaths.

More information on any of these adverse events can be found on novctrd.com. Use trial number **CLNA043A11101** to find the scientific summary.

What other results were learned?

How much and how fast LNA043 got into the blood?

The researchers wanted to know if LNA043 moved from the participants' knee joint into their blood. To find out, the trial doctors tested the participants' blood at different times after they got the injection.

Overall, the researchers found that after injection into the knee joint, only a small amount of LNA043 moved into their blood. This happened within a few hours. Participants who got the 40 mg injection of LNA043 had higher levels of LNA043 in their blood than those who got the 20 mg injection. On average, LNA043 was gone from the blood 3 days after getting the treatment.

Did the participants have antibodies against LNA043?

The researchers wanted to know if the participants had antibodies against LNA043. Antibodies are normally made by the immune system to find anything that does not belong in the body. This is how the body knows to fight infections by bacteria and viruses. Sometimes the immune system makes antibodies that can stop the treatment from working.

The researchers studied the participants' blood samples. They found that none of the participants in this trial had antibodies against LNA043.

What was learned from this trial?

This was the first trial to learn about the safety of LNA043 in Japanese participants. The clinical trial team concluded that a single injection of 20 mg or 40 mg of LNA043 into the knee joint had no safety concerns for the participants in this trial.

These are the results of a single trial. Other trials may have different results. This was one of many trials a drug must go through before it can be approved for doctors to prescribe.

Where can I learn more about this and future trials?

For more information about this trial, go to these websites:

- novctrd.com – search using the study number **CLNA043A11101**
- clinicaltrials.gov – search using the number **NCT04564053**

If more trials are planned, they can be found on the public websites above. When there, search for **LNA043** or **osteoarthritis**.

Full trial title: A randomized, participant and investigator blinded, placebo-controlled, single ascending dose study investigating the safety, tolerability and pharmacokinetics of LNA043 in Japanese participants with osteoarthritis of the knee



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



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