NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects and safety of omalizumab compared to placebo in people with a severe pollen allergy to Japanese cedar

Protocol number: CIGE025F1301

Thank You!

Novartis, the sponsor of this clinical trial, would like to thank you for taking part in this trial for the drug omalizumab, also known as IGE025. You helped researchers learn more about how omalizumab works in people with a severe pollen allergy to Japanese cedar.

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.

Important note: This summary only shows the results of a single clinical trial. Other clinical trials may have different findings. Researchers and health authorities 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 about 9 months. The trial started in December 2017 and ended in October 2018.

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

Why was the research needed?

Researchers are looking for a better way to treat severe Japanese cedar pollinosis that is not completely controlled by the currently available treatments. Japanese cedar pollinosis is a type of seasonal allergy caused by Japanese cedar pollen. This allergy affects around 30% of the people living in Japan. A majority of the people affected have severe symptoms that impact their daily activities. Symptoms include sneezing, runny nose, stuffy nose, and itchy and watery eyes. Even with the available treatments, some patients still report symptoms during the cedar pollen season.

Omalizumab is a drug that is already approved for treating asthma and hives caused by allergies. In previous clinical trials, it has been shown to help patients with cedar pollinosis. Researchers wanted to find out if giving this drug in addition to the other recommended treatments would help improve the symptoms of severe cedar pollinosis that are not completely controlled by the currently available treatments.

The main purpose of this trial was to find out if omalizumab improved cedar pollinosis symptoms in participants whose symptoms were not controlled by the available treatments.

Trial drugs

The drugs given in this trial were:

- **Omalizumab (IGE025)**: a drug that is approved for treating asthma and hives caused by allergies.
- **Placebo**: looks like the trial drug but does not have any medicine in it. Using a placebo helps researchers better understand the effect of a trial drug.

In addition to 1 of the 2 treatments above, participants were given other currently recommended treatments for cedar pollinosis.

Trial purpose

This trial was done to learn more about the effects and safety of omalizumab. The main question the researchers wanted to answer in this trial was:

- Was the total score for severity of sneezing, runny nose, and stuffy nose lower in participants who were given omalizumab compared with placebo?

Researchers also monitored the health of participants throughout the trial for any medical problems.

Who was in this trial?

The participants could take part in this trial if they:

- had a clinical history of Japanese cedar pollinosis that was not controlled by other medication,
- were between the ages of 12 and 75 years,
- had a body weight between 20 and 150 kilograms.

A total of 337 participants at 22 trial sites in Japan participated in this trial.

The average age of participants was 42 years. The age of the participants ranged from 12 to 74 years. About 58% of trial participants, equal to 196 out of 337, were females.

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 the participants were receiving. Some trials are done this way because knowing what treatment each participant 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?

At the start of the trial, the participants were randomly assigned to receive either:

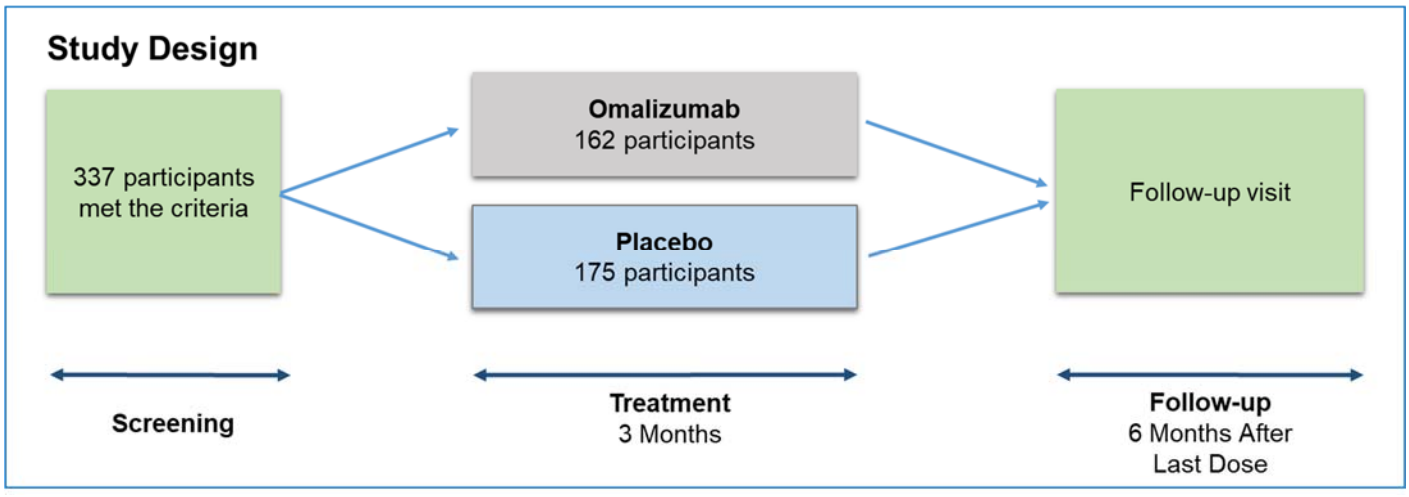
- **Omalizumab** as an injection under the skin every 2 or 4 weeks, at a dose of 75 to 600 mg. The dose depended on the participants' body weight and the levels of Immunoglobulin E (IgE) in their blood, which is related to allergy.
- **Placebo** as an injection under the skin every 2 or 4 weeks.

The dose and frequency of the treatment given was kept consistent for 3 months of the treatment period.

In addition to 1 of the 2 treatments mentioned above, the participants were given other recommended treatments for cedar pollinosis.

During the screening period, 1 to 5 weeks before taking either omalizumab or placebo, and during the treatment period, participants recorded their symptoms of sneezing, stuffy nose, and runny nose daily using a scale of 0 (no symptoms) to 4 (severe symptoms). Participants also recorded their symptoms of itchy and watery eyes on a similar scale of 0 to 4, and any additional medications they took. Researchers monitored the general health of participants throughout the trial.

Participants returned to their trial site 6 months after receiving their last dose of treatment for a follow-up visit. Blood samples were taken at this visit.



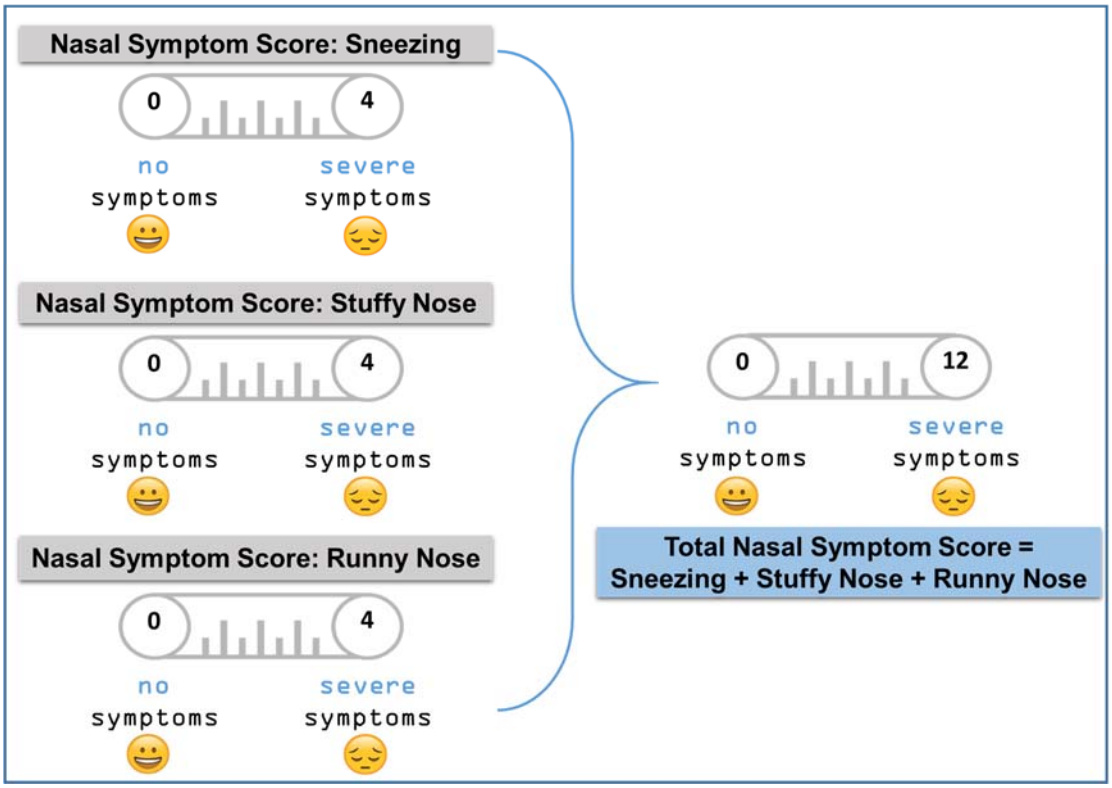
What were the key results of this trial?

This is a summary of the overall results for all participants in both 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. More details on the results can be found on the websites listed at the end of this summary.

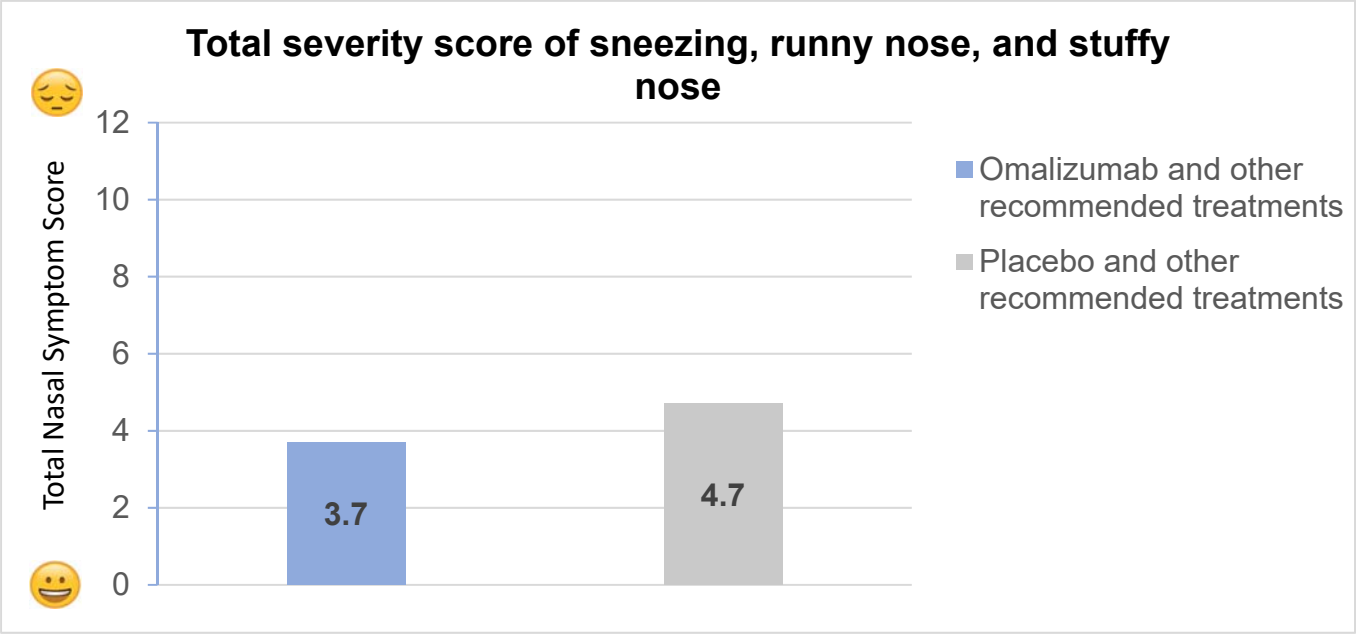
Results are reported for the severe symptom period, which was the 30-day period when the participants' allergy was most severe. Results were available for 158 participants who were given omalizumab and 174 participants who were given placebo.

Was the total score for severity of sneezing, runny nose, and stuffy nose lower in participants who were given omalizumab compared with placebo?

Throughout the study, participants recorded their symptoms of sneezing, stuffy nose, and runny nose daily using a scale of 0 (no symptoms) to 4 (severe symptoms). The total nasal symptom score is the sum of these 3 symptom scores and ranges from 0 (no symptoms) to 12 (most severe symptoms). This is shown in the figure below.



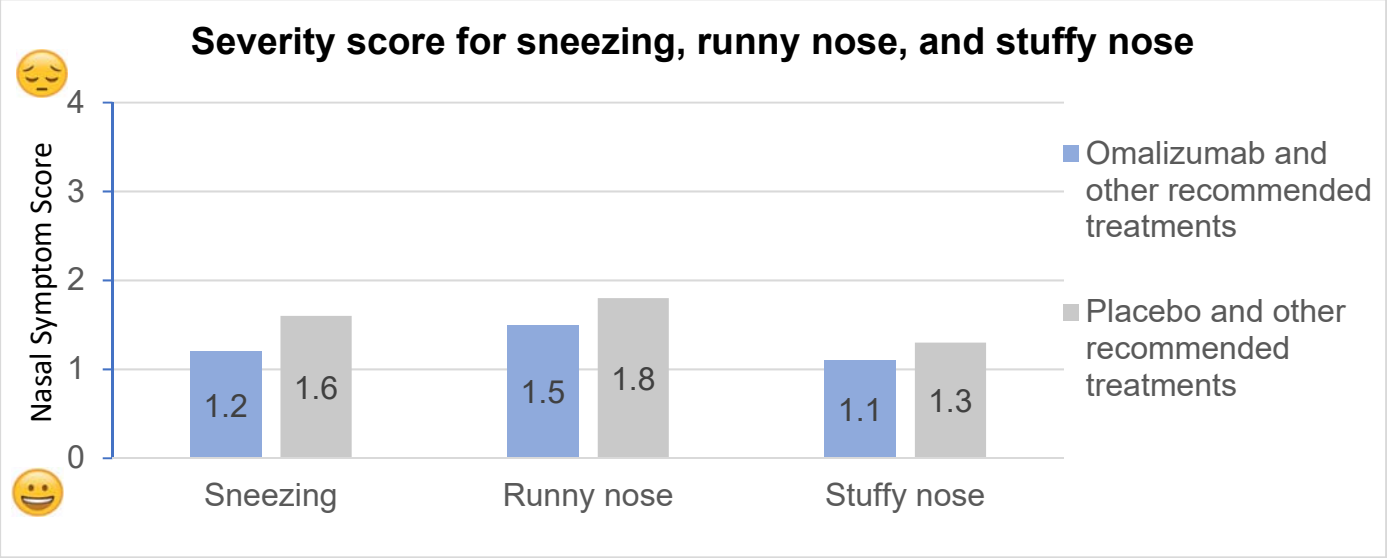
Researchers found that during the severe symptom period, participants who were given omalizumab and other recommended treatments had a lower total score compared with those who were given placebo and other recommended treatments – see the chart below.



What were the other results of this trial?

Was the severity of sneezing, runny nose, and stuffy nose lower in participants who were given omalizumab compared with placebo?

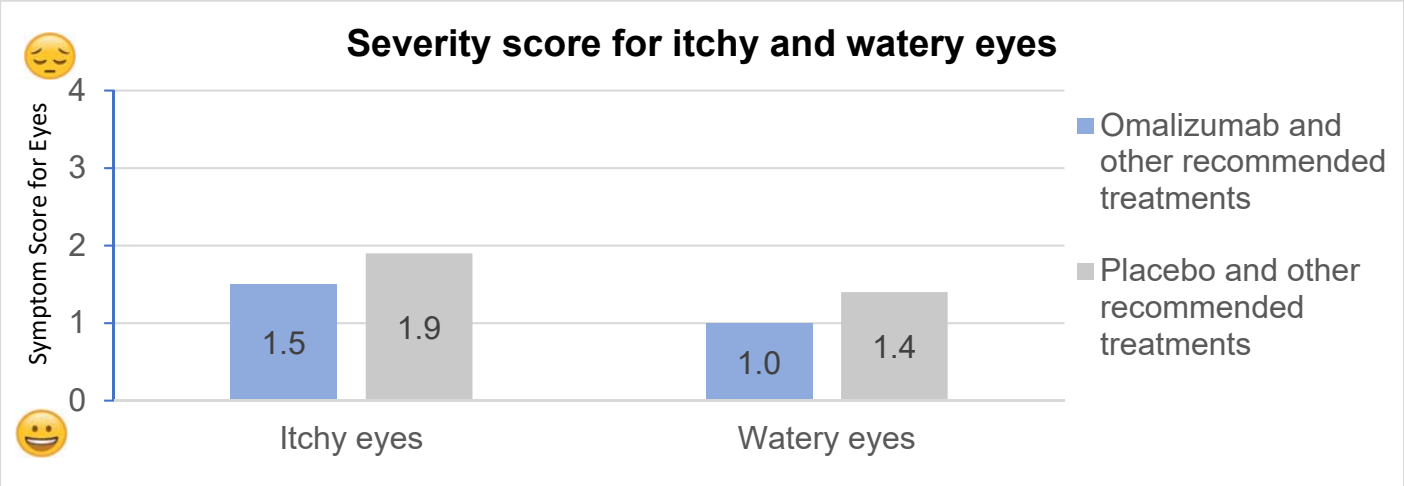
During the severe symptom period, the severity of sneezing, runny nose, and stuffy nose was lower in participants who were given omalizumab and other recommended treatments compared with those who were given placebo and other recommended treatments - see the chart on the next page.



Was the severity of itchy and watery eyes lower in participants who were given omalizumab compared with placebo?

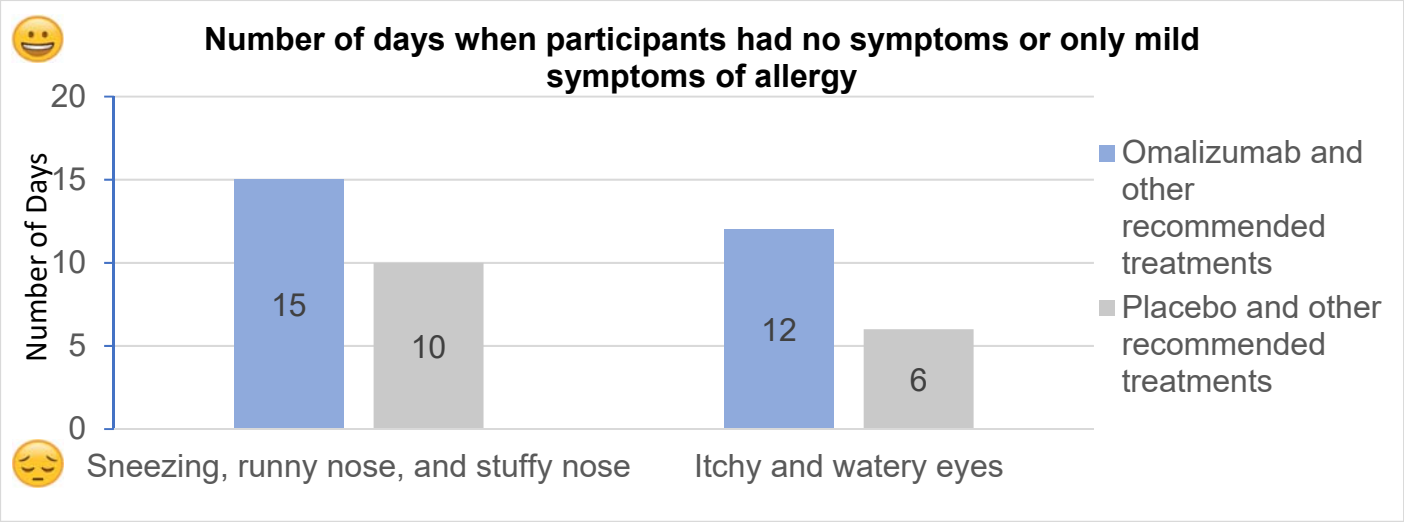
Participants recorded their symptoms of itchy and watery eyes daily using a scale of 0 (no symptoms) to 4 (severe symptoms).

During the severe symptom period, the severity of itchy and watery eyes was lower in participants who were given omalizumab and other recommended treatments compared with those who were given placebo and other recommended treatments - see the chart below.



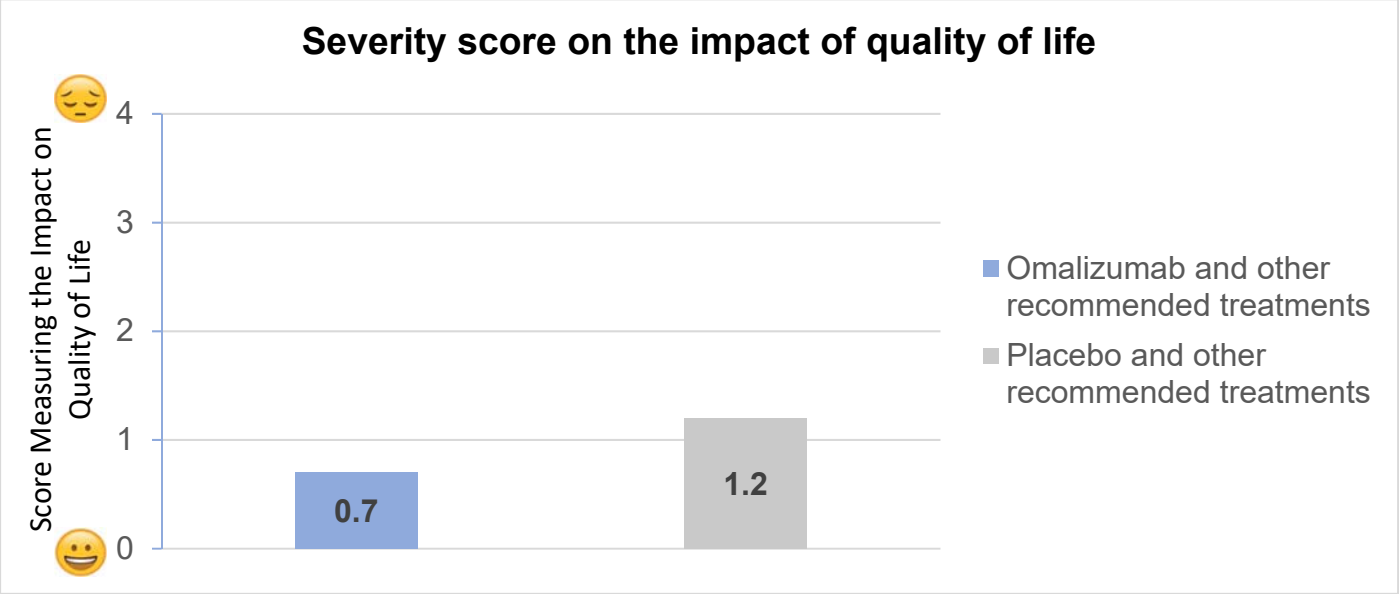
For how many days did the participants have no symptoms or only mild symptoms of allergy?

During the severe symptom period, participants who were given omalizumab and other recommended treatments had more days when they were free of symptoms or only had mild symptoms compared with those who were given placebo and other recommended treatments – see the chart below.



How did allergy symptoms impact the participants' quality of life?

Participants recorded the impact of their allergy symptoms on their ability to perform daily activities at home, school, or work, outdoor activities likes sports, their social life, their sleep, and their physical and emotional health using a scale of 0 (no impact/problem) to 4 (very high impact/great problem). During the severe symptom period, participants who were given omalizumab and other recommended treatments reported that their allergy had a lower impact on the quality of life compared with those who were given placebo and other recommended treatments. See the chart on the next page.



What medical problems did the participants have during the trial?

Medical problems that happen in clinical trials are called “adverse events”. An adverse event is an 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. These problems may or may not be caused by the trial drug.

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. So, when new drugs are being studied, researchers keep track of all adverse events the participants have.

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

What were the most common non-serious adverse events?

The most common non-serious adverse events that happened in at least 2% (2 out of 100) of participants in any group are listed in the table on the next page.

Most Common Non-Serious Adverse Events		
	Omalizumab	**Placebo**
Total number of participants	**161**	**175**
Total participants affected with the most common events	16% (26)	12% (21)
Common cold	9% (15)	5% (8)
Sore throat	4% (7)	3% (5)
Flu	3% (4)	5% (8)

What was the most common serious adverse event?

One participant (less than 1%) in the omalizumab group was diagnosed with cancer of the testicles. No participants in the placebo group experienced any serious adverse events. There were no deaths reported during this trial.

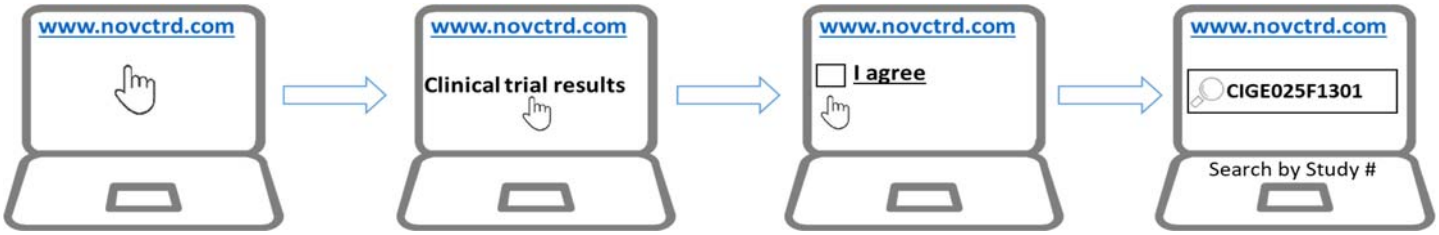
How was this trial useful?

This trial helped researchers learn how well omalizumab works and if it is safe to use in people with severe Japanese cedar pollinosis that is not completely controlled by the currently available treatments. Results from this trial may be used to seek approval to give omalizumab to people with Japanese cedar pollinosis.

Please remember, this summary only shows the results of a single clinical trial. Other clinical trials may have different results. Researchers and health authorities 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.

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 websites:

- www.clinicaltrials.gov. Use the NCT identifier NCT03369704 in the search field.
- www.clinicaltrialsregister.eu. Use the EudraCT identifier 2017-002154-36 in the search field.

Full clinical trial title: A 12 week, multi-center, randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy and safety of omalizumab in adult and adolescent patients with inadequately controlled severe Japanese cedar pollinosis despite the current recommended therapies

Thank you

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

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

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www.novartisclinicaltrials.com