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 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.

Glossary of words

Adverse events
medical problems that happen during clinical trials are called ‘adverse events’

Allergy
a response by the body to an ordinarily harmless substance like food, pollen, dust, etc.; these substances are called allergens

Clinical trial
a research investigation, in which people volunteer to participate, to evaluate the effects of new drugs

Double-blind trial
a type of clinical trial in which trial participants, trial doctors, or trial staff do not know what medicine the participants receive in the clinical trial

Omalizumab
a drug developed to reduce the body’s response to allergens. It is already permitted for treating allergic conditions like asthma and hives; it is injected under the skin

Placebo
a dummy medicine which looks like the trial drug but does not have any medicine in it

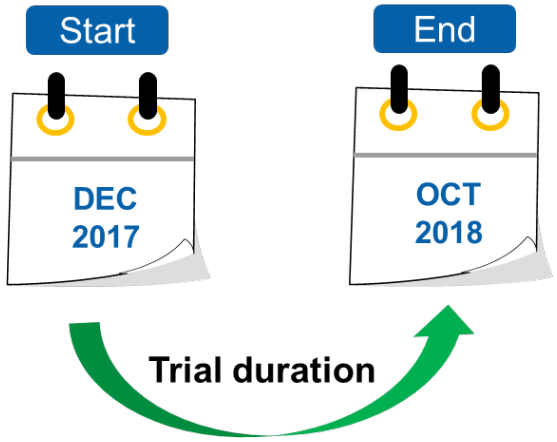
Pollen
a fine to coarse powdery substance which triggers allergies

Researchers
someone who conducts experiments, in this trial it is the hospital doctor, trial staff, etc.

Symptoms
an abnormal feeling or change in a body function which is apparent to patient

Trial drug
drug being studied or researched in a clinical trial

How long was this trial?

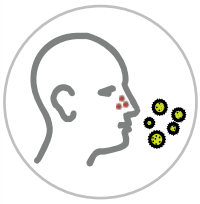


The trial was designed so that an individual participant could take part for about 9 months. The trial started in December 2017 and ended in October 2018.

The researchers completed the trial as planned. This summary is based on the report of the trial results.

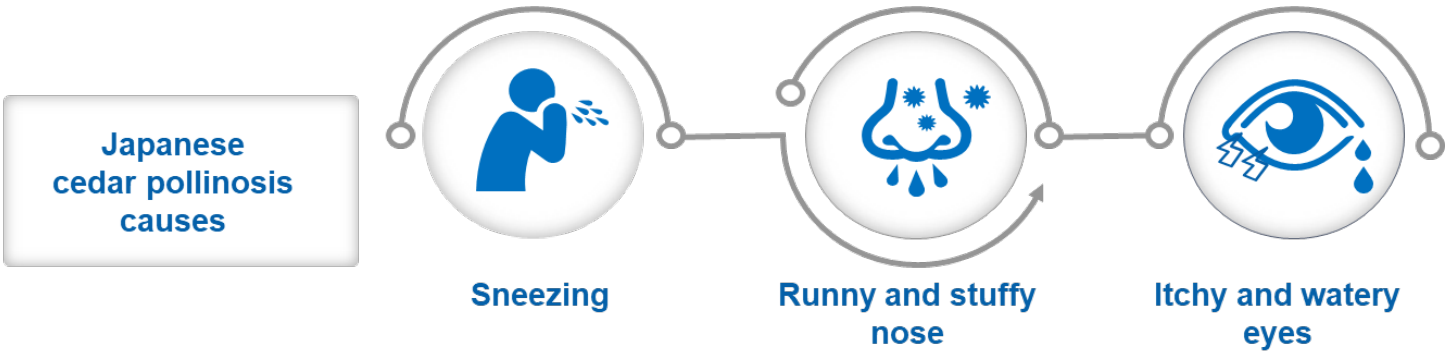
Why was the research needed?

Cedar pollinosis



Japanese cedar tree releases fine-to-coarse powdery yellow substance called pollens which causes a type of hypersensitive reaction, allergy, at certain times of the year. This allergy is known as **Japanese cedar pollinosis**. This affects around 30% of people living in Japan.

Most people are treated with other drugs but some still report having allergy symptoms during the cedar pollen season.



Purpose of trial

This trial was done to learn more about the effects and safety of omalizumab, also called IGE025, and seek an answer to the question:

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 medical problem of participants throughout the trial.

Trial drugs

Omalizumab (IGE025)

A drug that is available for treating asthma and hives caused by allergies.

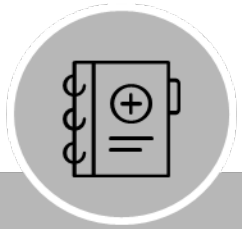
Placebo

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 current recommended drugs for cedar pollinosis during the treatment period.

Who was in the trial?



People with history of **Japanese cedar pollinosis** not-controlled by other drugs

People between **12 and 75** years

People weighing between **20 and 150** kg

What kind of trial was this?

Double-blind trial

None of the trial participants, trial doctors, or trial staff knew what treatment 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?

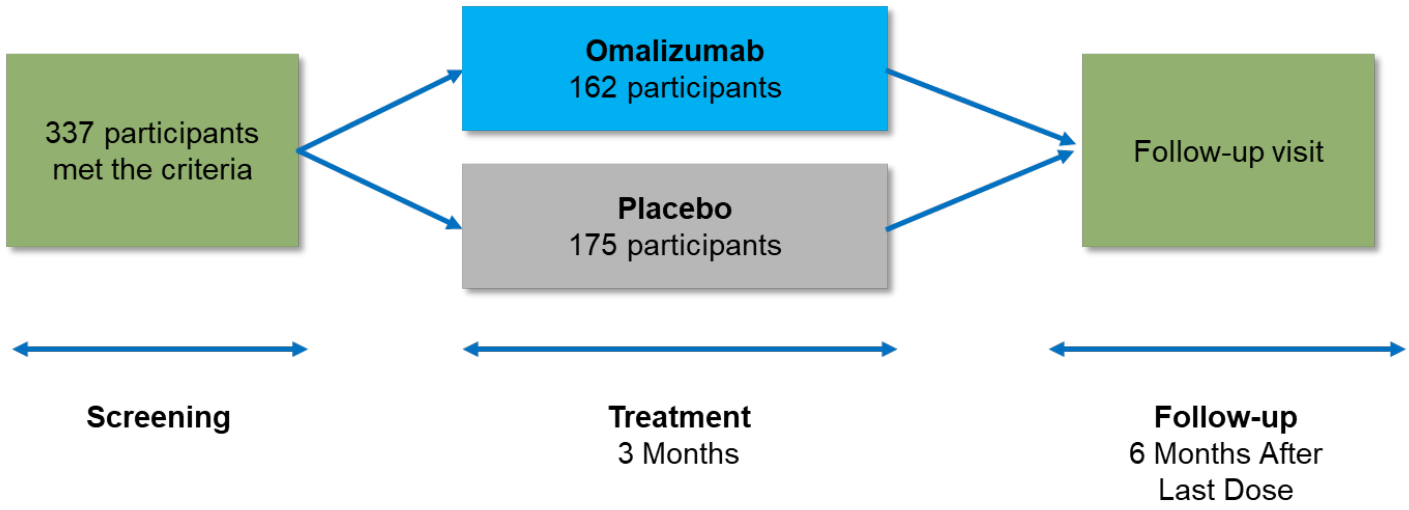
At the start of the trial, the participants were randomly assigned to receive either:

- **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 severity of their allergies.
- **Placebo** as an injection under the skin every 2 or 4 weeks.

The dose and frequency of the treatment given was kept consistent for the rest of the 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.

Study Design



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.

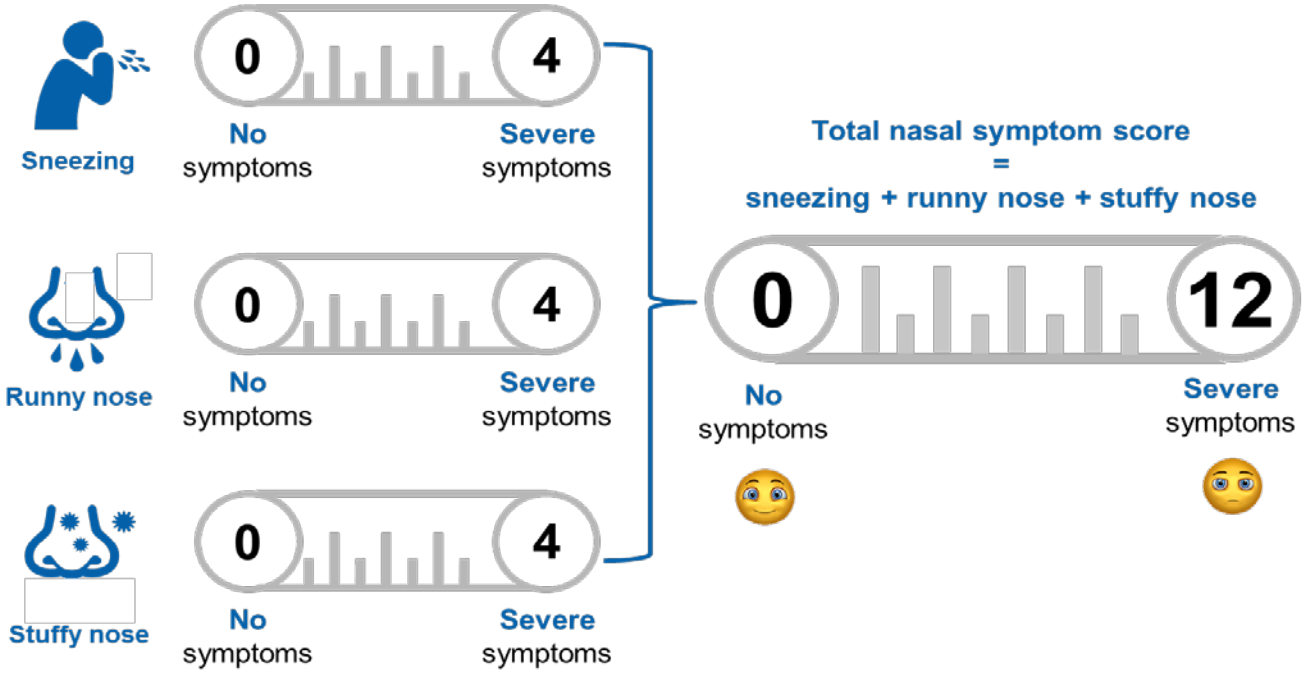
Results are reported for the severe symptom period, which was the 30 day period when the participants' allergy was most severe. Results were available for 158 participants who were given omalizumab and 174 participants who were given placebo.

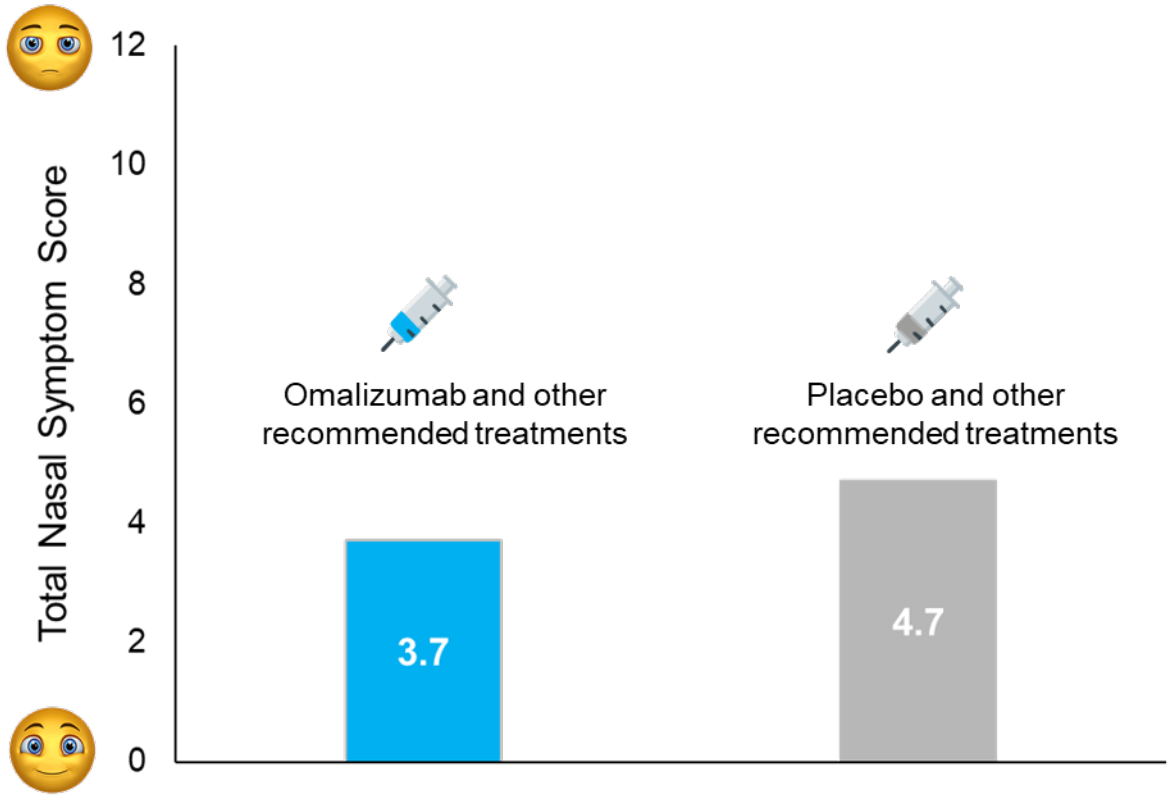
Was the total score for severity of sneezing, runny nose, and stuffy nose lower in participants who were given omalizumab compared with placebo?

Yes, the total score of severity of sneezing, runny nose and stuffy nose was lower in participants who were given omalizumab compared with placebo.

Throughout the study, participants recorded their daily symptoms of sneezing, stuffy nose, and runny nose using a scale of **0** to **4**.

The total nasal symptom score is the sum of these three symptom scores and ranged from **0** to **12**.



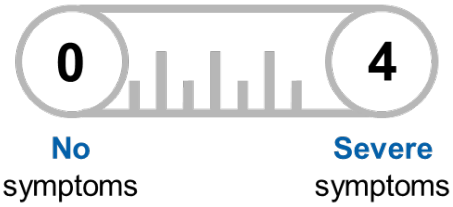


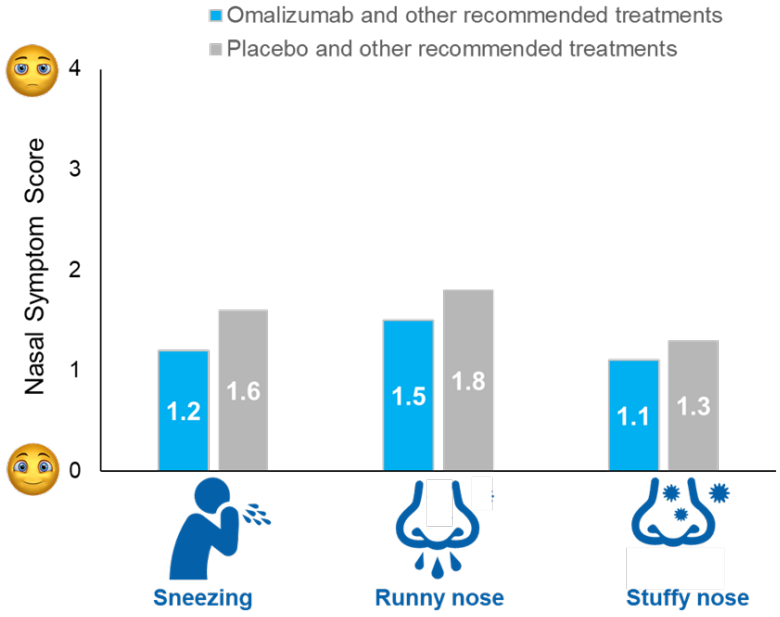
What were the other results of this trial?

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

Yes, the severity of sneezing, runny nose and stuffy nose was lower in participants who were given omalizumab compared with placebo.

Throughout the study, participants recorded their daily symptoms of sneezing, stuffy nose, and runny nose using a scale of **0** to **4**.

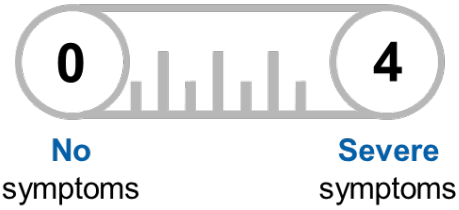


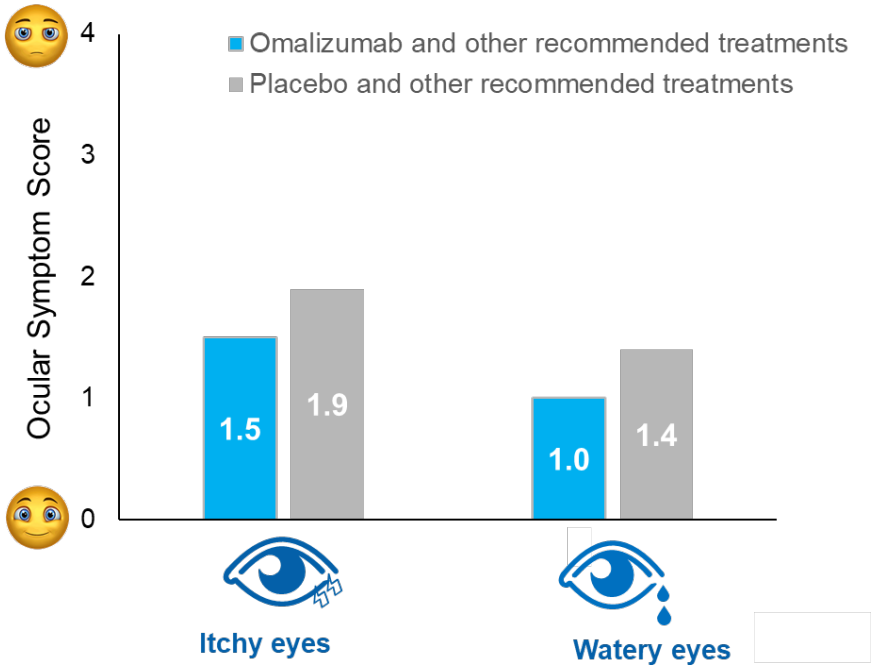


Was the severity of itchy and watery eyes lower in participants who were given omalizumab compared with placebo?

Yes, the severity of itchy and watery eyes was lower in participants who were given omalizumab compared with placebo.

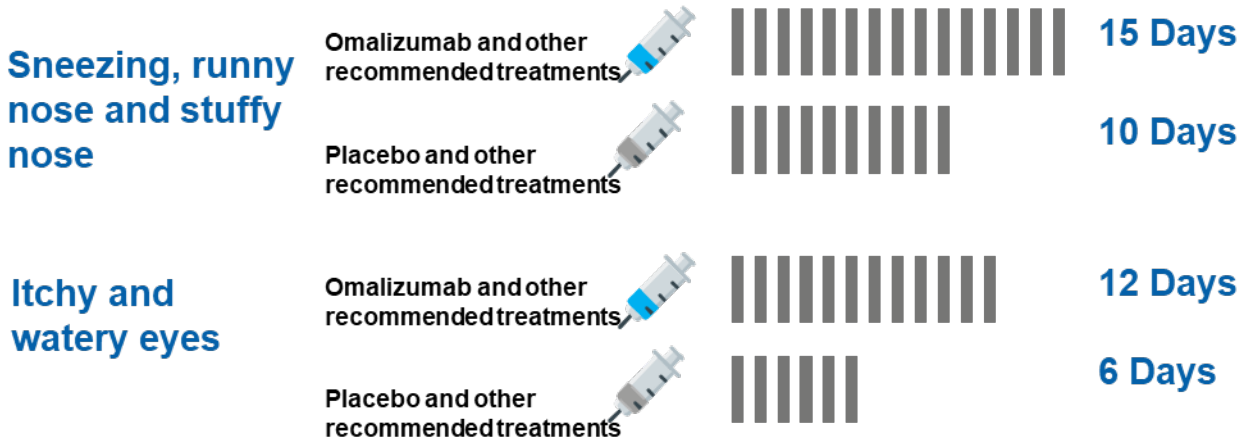
Throughout the study, participants recorded their daily symptoms of itchy and watery eyes using a scale of **0** to **4**.





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

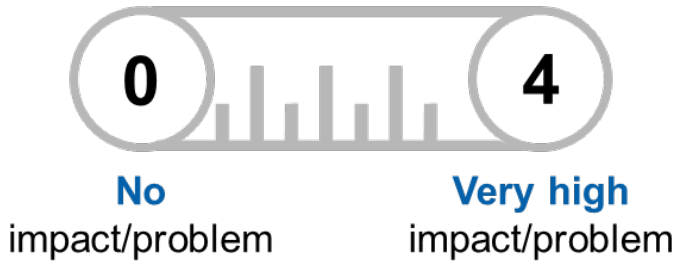
During the severe symptom period, participants who were given omalizumab and other recommended treatments had more days when they were free of symptoms or only had mild symptoms compared with those who were given placebo and other recommended treatments.

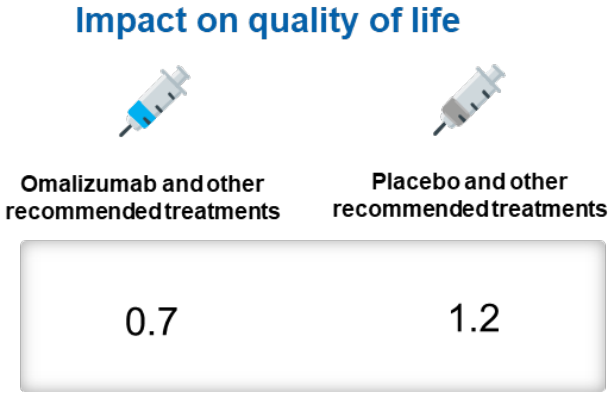


Number of days when participants had no symptoms or only mild symptoms of allergy

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** to **4**.





What medical problems did the participants have during the trial?

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

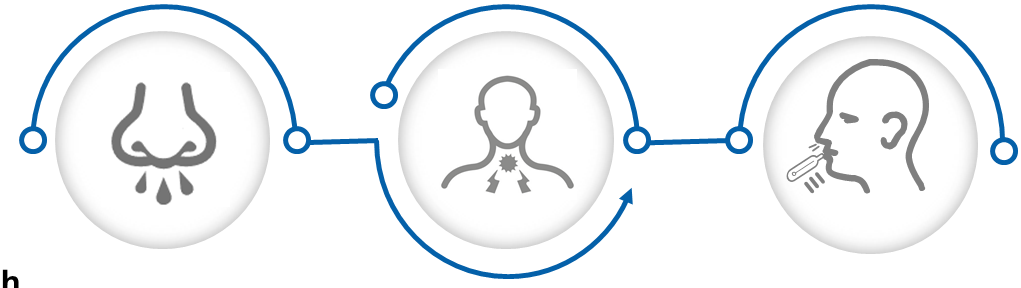
A lot of research is needed to know whether a drug causes an adverse event. During a trial, all adverse events are recorded, whether or not they are thought to be caused by the trial drug. So, when new drugs are being studied, researchers keep track of all adverse events participants have.

An adverse event is an unwanted sign or 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

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 that happened in at least 2% (2 out of 100) of participants?



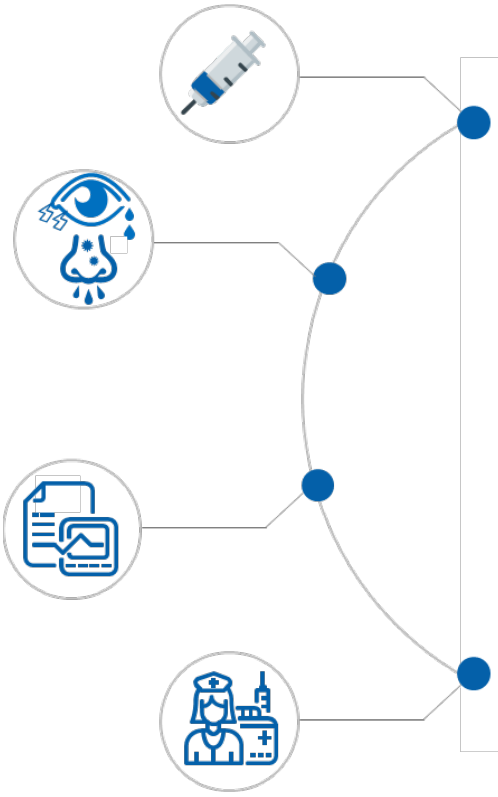
Participants affected with most common events		Common cold	Sore throat	Flu
Omalizumab	16% (26/161)	9% (15)	4% (7)	3% (4)
Placebo	12% (21/175)	5% (8)	3% (5)	5% (8)

Number and percentage of participants with most common non-serious adverse events

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 duting this trial.

How was this trial useful?

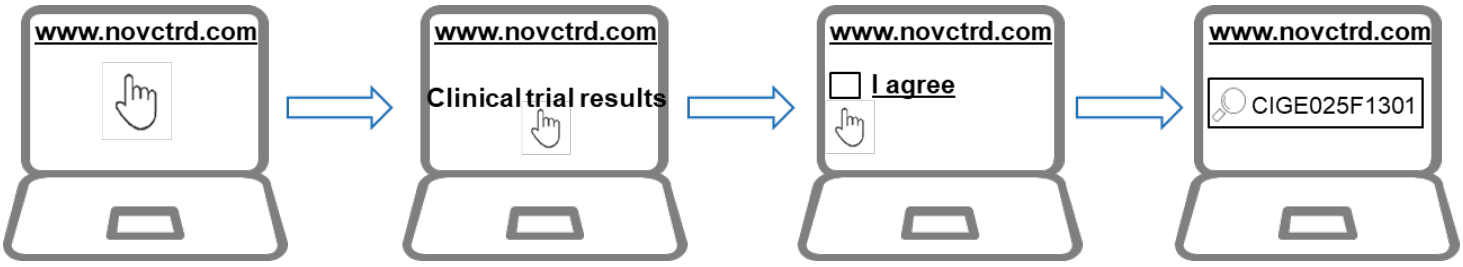


This trial helped researchers learn how well omalizumab, also known as IGE025, works and if it is safe to use in people with severe cedar pollinosis that is not completely controlled by the currently available treatments. Results from this trial may be used to seek permission for use of omalizumab in people with severe cedar pollinosis.

Please remember, this summary only shows the results of the single clinical trial that you participated in. 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.

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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