Clinical Trial Results Summary

NOVARTIS

The breathing effects and safety of CSJ117 for people with mild allergic asthma

Thank you!

Thank you to the participants who took part in the clinical trial for the trial drug **CSJ117**. All of the participants helped the researchers learn more about how CSJ117 works and how safe it is to take.

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. An independent organization prepared this summary of the trial results.

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

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

Trial information

Trial number: CCSJ117X2201
Drug studied: CSJ117
Sponsor: Novartis

You can find **more information** about this trial by going to the websites listed on **pages 11-12** of this summary.

This trial at a glance

What was the purpose of this trial?

Read more on **page 3**

The purpose of this trial was to find out:

- What medical problems the participants had during this trial. Keeping track of the medical problems helped to learn about the safety of CSJ117.
- If the participants who took CSJ117 could breathe easier after breathing in allergens, such as dust or pollen

Who was in this trial?

Read more on **pages 3-4**

- 28 men and women were in this trial
- Every participant in this trial was 19 to 57 years old and had mild allergic asthma

What treatments did participants take?

Read more on **page 4**

Each participant was assigned one of these treatments:

- **CSJ117**
- **Placebo** – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

The participants took their assigned treatment using a **powder inhaler**.

What were the main results of this trial?

Read more on **pages 6-10**

Most of the participants had medical problems during this trial – none were considered serious. A similar number of participants in each treatment group had medical problems. The most common medical problem was headache.

On average, the participants who took CSJ117 could breathe easier compared to those who took the placebo after breathing in allergens.

Read about other results of this trial on **page 10**

What was the purpose of this clinical trial?

Researchers are looking for better ways to treat allergic asthma. **Allergic asthma** is a disease that causes the airways of the lungs to swell after breathing in allergens, such as pet dander, dust, or pollen.

The symptoms of allergic asthma make it harder for a person to breathe. These symptoms often happen as soon as someone breathes in allergens, and may happen again 3 to 7 hours later.

What are some common asthma symptoms?

- Shortness of breath: feeling like you can't breathe fast enough or deeply enough
- Wheezing: a high-pitched whistling sound while breathing
- Coughing
- Chest tightness

There is currently no cure for allergic asthma, but different types of medicines can help lessen the symptoms and make it easier to breathe.

CSJ117 is a trial drug designed to block an immune system protein involved in allergic asthma. The clinical trial team wanted to find out if blocking this protein with CSJ117 would lessen allergic asthma symptoms, which means it would be easier to breathe.

For this trial, the clinical trial team focused on the participants' breathing from 3 to 7 hours after breathing in allergens. These results can predict how well the trial drug may work overall.

Before a drug can be approved for doctors to prescribe, researchers do many trials to find out how safe it is and how well it works.

The main questions this trial was designed to answer:

- What medical problems did the participants have in this trial? Keeping track of the medical problems helped to learn about the safety of CSJ117.
- Could the participants who took CSJ117 breathe easier after breathing in allergens?

Who was in this trial?

28 participants were in this trial – 17 women and 11 men. Everyone was 19 to 57 years old. Their average age was 33.

Every participant in this trial had mild allergic asthma. They also:

- Had asthma symptoms soon after breathing in allergens, and 3 to 7 hours later
- Did not need hospital care because of their asthma during the 6 months before the trial
- Could continue to use a rescue inhaler and certain over-the-counter medicines
- Were in otherwise good overall health

This trial took place in Canada and Germany.

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, gender, and race

Use trial number **CCSJ117X2201** to find the scientific summary.

What treatments did the participants take?

A computer program was used to randomly assign each participant the treatment they took:

- **CSJ117**, 4 milligrams (mg)
- **Placebo** – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

Using a computer program to assign the treatments helped make sure the team compared the results as fairly as possible.

The participants took their assigned treatment one time a day for 12 weeks using a **powder inhaler**.

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

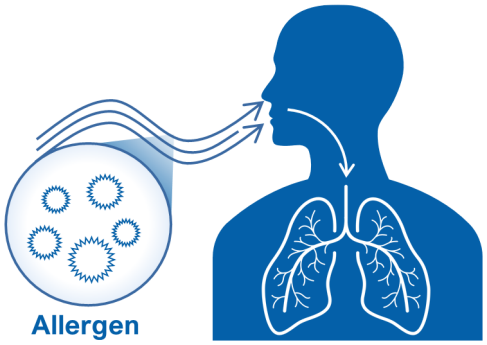
What happened during this trial?

The trial began in December 2017 and ended in July 2019. One participant did not complete this trial.

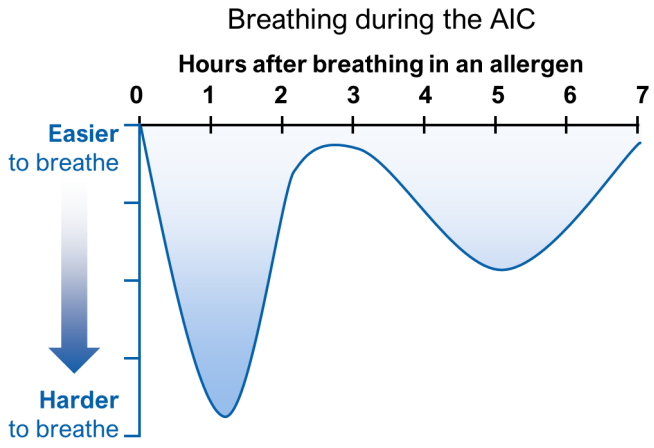
Researchers stopped this trial early because the sponsor had enough data on the effects of CSJ117 for people with mild allergic asthma. The sponsor wanted to focus on the effects of CSJ117 in people with severe allergic asthma.

During certain visits, the trial staff measured how easily the participants could breathe as soon as they breathed in allergens, and again 3 to 7 hours later. To do this, they used the **allergen inhalation challenge (AIC)**, a test to measure how easily a person can breathe over time after breathing in an allergen. An allergen usually makes it harder for someone to breathe. The clinical trial team wanted to find out if CSJ117 made it easier for the participants to breathe during the AIC.

Here's what happened during the allergen inhalation challenge (AIC):



A participant breathed in increasing amounts of an **allergen** chosen for them based on a skin prick test.



Over the next 7 hours, the trial staff measured **how easily the participant could breathe.**

The participant could take medicines to lessen their allergic asthma symptoms, if needed.

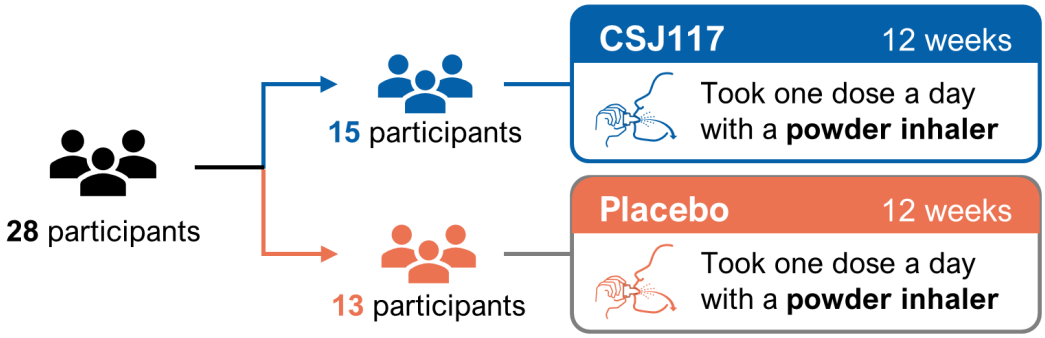
The participants went through the AIC 3 times during this trial: before treatment, during treatment, and at the end of treatment.

Here's how this trial was done:

Before treatment

- The trial doctors checked each participant's health to make sure they could be in this trial
- The trial staff measured each participant's breathing during the AIC

During treatment



- After 6 and 12 weeks of treatment, the trial staff measured each participant's breathing during the AIC
- Each participant could continue to take certain asthma medicines as needed, except before the AIC

After treatment

- The participants returned to the trial site for a health check at 1 week, 2 weeks, and 1 month after their final treatment

Throughout the trial, the trial staff looked for medical problems when they checked the participants' health. The participants also reported medical problems.

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 the trial?

Medical problems that happen during trials are called “adverse events”. An **adverse event** is any unwanted sign or symptom that participants have during a trial. An adverse event is 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. 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 might not be related to the trial treatments.

79% of the participants (22 of 28 participants) had adverse events during this trial – none were considered serious. A similar number of participants in each group had adverse events. The most common adverse event was headache.

Trial doctors looked for adverse events when they checked the participants’ health. The participants also reported adverse events.

Participants who had adverse events

Participants who had:	CSJ117 Out of **15** participants	Placebo Out of **13** participants
Serious adverse events	**0%** **0** of **15**	**0%** **0** of **13**
Non-serious adverse events	**67%** **10** of **15**	**92%** **12** of **13**
Left this trial due to adverse events	**0%** **0** of **15**	**0%** **0** of **13**

What serious adverse events did the participants have?

During this trial, no serious adverse events were reported, including deaths.

What non-serious adverse events did the participants have?

79% of the participants (22 of 28 participants) had adverse events that were not serious. The table below shows the non-serious adverse events that happened to **3 or more participants**. Other non-serious adverse events were reported by fewer participants.

Non-serious adverse events

	CSJ117 out of **15** participants	Placebo out of **13** participants
Headache	**27%** 4 of 15	**23%** 3 of 13
The common cold Nasopharyngitis	**13%** 2 of 15	**23%** 3 of 13
Throat pain Oropharyngeal pain	**13%** 2 of 15	**23%** 3 of 13
Cough	**13%** 2 of 15	**15%** 2 of 13
Back pain	**7%** 1 of 15	**15%** 2 of 13
Stuffy nose Rhinitis	**13%** 2 of 15	**8%** 1 of 13
Throwing up Vomiting	**20%** 3 of 15	**0%** 0 of 13

For more information about the adverse events the participants in this trial had, visit novctrd.com. Use trial number **CCSJ117X2201** to find the scientific summary.

Could the participants who took CSJ117 breathe easier after breathing in allergens?

On average, the participants who took CSJ117 could breathe easier compared to those who took the placebo 3 to 7 hours after breathing in allergens.

To find this out, the trial staff used a measure called Forced Expiratory Volume during 1 second, also called **FEV_1**. This is how much air a participant could blow out (exhale) with force in 1 second. Asthma symptoms lower a participant's FEV_1.

A **lower FEV_1** means it is **harder** to breathe**.**

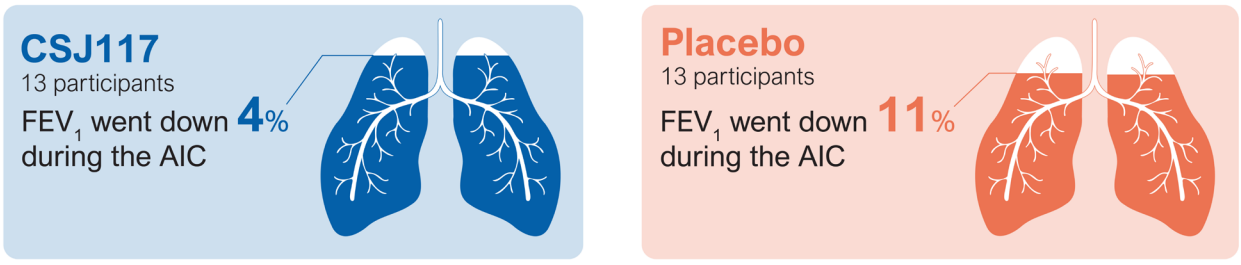
The clinical trial team looked at the overall change in the participants' breathing during the allergen inhalation challenge (AIC):

1. The trial staff measured each participant's **FEV_1** many times during the AIC
2. The team calculated each participant's overall change in FEV_1 during hours 3 to 7 of the AIC compared to before the AIC
3. Then, the team compared the overall change in FEV_1 for participants who took CSJ117 to those who took the placebo

The graph below shows the average overall change in the participants' breathing during hours 3 to 7 of the AIC for those who finished 12 weeks of treatment. Overall, the participants who took CSJ117 could breathe easier during this time compared to those who took the placebo.

Overall change in breathing (FEV_1)

Below shows the average change in the participants' FEV_1 during hours 3 to 7 of the AIC compared to before the AIC. These results are after 12 weeks of treatment.



A **lower** FEV_1 means it is **harder** to breathe

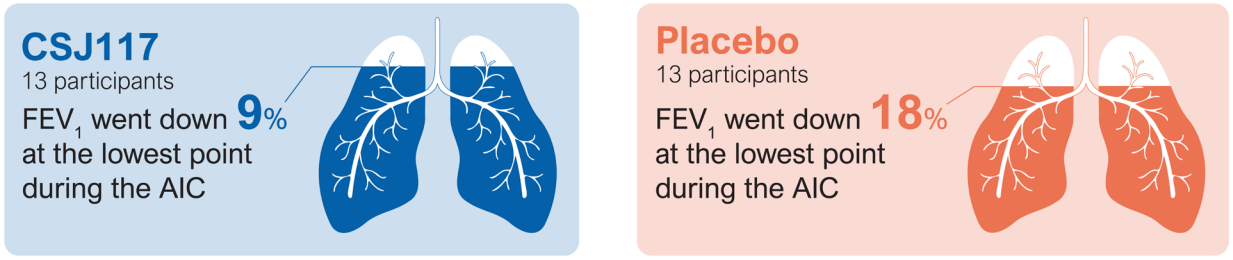
The clinical trial team also looked at how the participants' breathing changed when it was hardest for them to breathe during the AIC:

1. The team looked at each participant's **lowest FEV_1** during hours 3 to 7 of the AIC
2. The team compared this to the participant's FEV_1 before the AIC to calculate their largest drop in FEV_1
3. Then, the team compared the largest drop in FEV_1 for participants who took CSJ117 to those who took the placebo

Lowest FEV_1 shows the least amount of air they could breathe out, which means it was hardest for them to breathe.

Largest drop in breathing (FEV_1)

Below shows the average of the participants' lowest FEV_1 during hours 3 to 7 of the AIC compared to before the AIC. These results are after 12 weeks of treatment.



A **lower** FEV_1 means it is **harder** to breathe

What other results were learned?

The clinical trial team measured participants' breathing after they took their assigned treatment for 6 and 12 weeks.

After 6 weeks of treatment, the participants who took CSJ117 had **no change** in their breathing during the AIC compared to the participants who took the placebo.

After 12 weeks of treatment, the participants who took CSJ117 could **breathe easier** during the first 2 hours of the AIC compared to the participants who took the placebo. The clinical trial team concluded that more trials are needed to know if this difference was meaningful.

What was learned from this trial?

This was the first trial to learn about how well CSJ117 works and how safe it is for people with mild allergic asthma.

The clinical trial team found that the participants who took CSJ117 could breathe easier 3 to 7 hours after breathing in allergens. They also found it was safe for the participants in this trial. After learning this, the sponsor stopped this trial early to focus on people with severe allergic asthma.

This type of trial learns about the safety of a trial drug and if it could work to treat the condition in people. This was one of many trials a drug must go through before it can be approved for doctors to prescribe.

The results presented here are for one trial. One trial cannot give a complete picture of the benefits and risks of a trial drug. The results of many trials are needed to find out which treatments can be used for people with allergic asthma. This summary shows only the main results from this trial. Other trials may provide new information or different results.

Where can I learn more about this and future clinical trials?

This is a summary of the results for one trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on “Trial summary for patients” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Select “Search by study number” on the bottom left of the page
5. Type **“CCSJ117X2201”** in the search box and click search

If you would like to view the website in a language other than English, you can click the “Google Translate” button on the top right of the page.

If you were in this trial and have questions about the results, please speak with the doctor or staff at your trial site.

This trial was registered on the following website:

- ClinicalTrials.gov – https://clinicaltrials.gov/

To find this trial, type **CCSJ117X2201** in the **Other terms** search box

Full trial title:

A randomized, subject- and investigator-blinded, placebo-controlled, parallel-design, broncho-provocation study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses of inhaled CSJ117 in adult subjects with mild atopic asthma

If more trials are planned, they will appear on the public websites listed above. When there, search for **CSJ117.**

Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The participants made this clinical trial possible and helped researchers answer important health questions and learn about a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.

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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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