

The effects on breathing and safety of trial drug QVM149 compared to a standard asthma treatment



Thank you!

Thank you to the participants who took part in the clinical trial for the drug **QVM149**. All of the participants helped the researchers learn more about QVM149 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.

Trial information

Trial number: CQVM149B2208

Drug studied: QVM149

Sponsor: Novartis

You can find **more information** about this trial by going to the websites listed on **page 10** of this summary.



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 overview

What was the purpose of this trial?

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This trial was designed to learn about the effects on breathing and safety of the trial drug QVM149. The trial compared QVM149 to a standard asthma treatment.

This trial was designed to answer these questions:

- Could the participants breathe easier after they took QVM149 compared to after they took a standard asthma treatment?
- What medical problems did the participants have?
Keeping track of the medical problems helped to learn about the safety of QVM149.

Who was in this trial?

[Read more on page 3](#)



- 116 men and women were in this clinical trial
- All the participants had asthma for at least 1 year

What treatments did the participants take?

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The participants took all 3 of these treatments in different orders:

- Larger dose of QVM149
- Smaller dose of QVM149
- Standard asthma treatment

The participants took these treatments using a **powder inhaler**.

What were the main results of this trial?

[Read more on page 5](#)



- The participants could breathe easier after they took either dose of QVM149 compared to after they took the standard asthma treatment
- The clinical trial team concluded there was no meaningful difference in the safety of QVM149 compared to the standard asthma treatment

What was the purpose of this trial?

Researchers are looking for a better way to treat asthma. Asthma is a disease that causes the airways of the lungs to swell, making it hard to breathe.

The symptoms of asthma include:

- 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 asthma, but different types of medicines can help people with asthma breathe easier. Some people may need more than one type of medicine for their asthma. QVM149 is a mix of 3 medicines that are approved for doctors to prescribe separately to treat asthma or COPD, also called chronic obstructive pulmonary disease. These medicines are: indacaterol, glycopyrronium, and mometasone. At the time of this clinical trial, QVM149 was not an approved medicine.

This trial compared QVM149 to a standard asthma treatment, an approved mix of 2 medicines: salmeterol and fluticasone. Before a drug can be approved for patients to take, researchers do many clinical trials to find out how safe it is and how it works.

This trial was designed to answer these questions:

- Could the participants breathe easier after they took QVM149 compared to after they took a standard asthma treatment?
- What medical problems did the participants have?

Who was in this trial?

116 participants began the trial – 61 men and 55 women. Everyone was 18 to 76 years old. Their average age was 50.

Every participant in this clinical trial had asthma for at least 1 year.

This clinical trial took place in Bulgaria, China, Germany, the Netherlands, Romania, and the United Kingdom.



For more information about who could and could not be in this trial, and the participants in this trial, visit novctrd.com. Use trial number **CQVM149B2208** to find the scientific summary.

What treatments did the participants take?



Each participant took all 3 treatments in different orders. A computer program was used to randomly assign the order a participant took each of these treatments:

- **Larger dose** of QVM149
- **Smaller dose** of QVM149
- **Standard** asthma treatment

The participants took these treatments using a powder inhaler.

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

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

The participants received 2 inhalers to use each day during treatment. This was because QVM149 and the standard asthma treatment use different inhalers. The inhalers delivered either QVM149, the standard asthma treatment, or no treatment. The inhalers with no treatment helped to make sure no one knew the order that a participant took their assigned treatments.

For more information about the amount of each medicine in QVM149 and the standard asthma treatment, look at page 8 of this summary.

What happened during this trial?

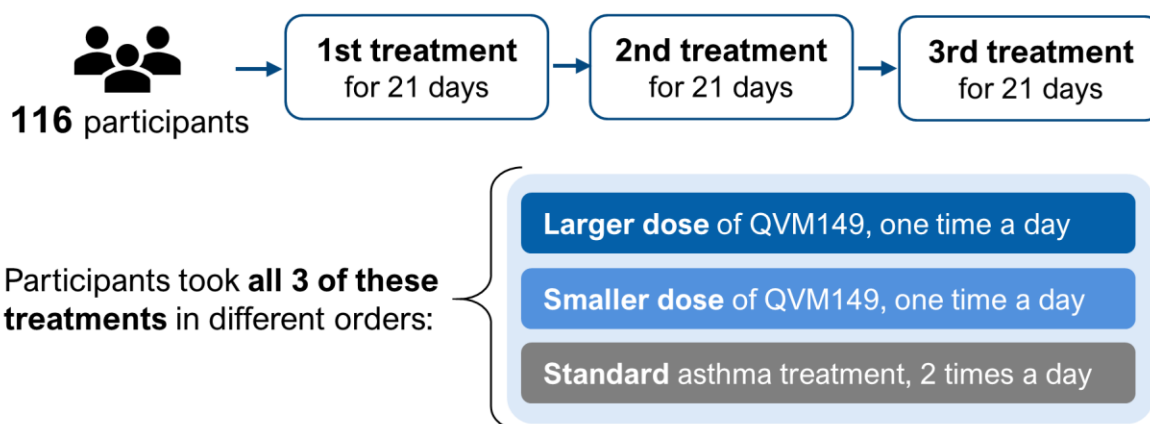
The trial began in January 2017 and ended in August 2018. 9 participants did not complete this trial. The chart on the next page shows how this trial was designed.

Here's how this trial was designed:

Before treatment

- During a 14-day period, trial doctors checked each participant's health and asthma to make sure they could be in this trial
 - Trial doctors asked participants to stop taking certain medicines before they took any treatment in the trial
-

During treatment



After treatment

- After each 21-day period, trial doctors checked each participant's health and asthma before starting the next treatment
 - After a participant took their last treatment, trial doctors checked their health and asthma again
-

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.

Could participants breathe easier after they took QVM149 compared to after they took a standard asthma treatment?



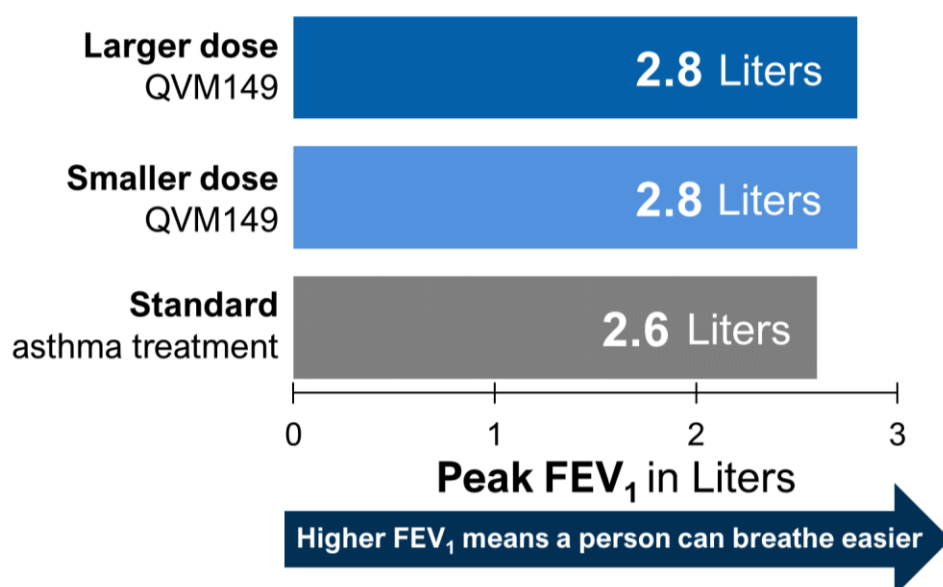
Participants could breathe easier after they took either dose of QVM149 compared to after they took the standard asthma treatment.

To check if the participants could breathe easier, the clinical trial team used a measurement called Forced Expiratory Volume during 1 second, also called **FEV₁**. This is how much air a person can blow out (exhale) with force in 1 second. Asthma narrows the airways in the lungs and lowers the amount of air a person can exhale. **A higher FEV₁ means that a person can breathe easier.**

After a participant took their assigned treatment for 21 days, trial doctors measured their FEV₁ many times over 24 hours. The clinical trial team then looked for each participant's highest FEV₁, called their **peak FEV₁**. The team compared the average of the participants' peak FEV₁ measures after each treatment.

The average of the participants' peak FEV₁ was higher after they took either dose of QVM149 compared to after they took the standard asthma treatment.

Average of the participants' peak FEV₁ after each treatment



What medical problems did participants have during the trial?

Medical problems that happen during clinical 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, or the participant needs hospital care.



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 happened in trials, even if they do not think the adverse events might be related to the trial treatments.



The clinical trial team concluded there was no meaningful difference in the safety of QVM149 compared to the standard asthma treatment.

Trial doctors looked for any adverse events when they checked the participants’ health. Participants also reported adverse events. The clinical trial team compared the adverse events participants had while they took QVM149 to those they had while they took the standard asthma treatment. The table below shows the adverse events for any participant that took the treatment at least one time. Because 9 participants didn’t complete this trial, the total number of participants who took each treatment is different.

Participants who had adverse events

Participants who had:	Larger dose QVM149 (out of 112 participants)	Smaller dose QVM149 (out of 115 participants)	Standard asthma treatment (out of 111 participants)
Adverse events	33% (37)	29% (33)	38% (42)
Serious adverse events	0% (0)	0% (0)	0% (0)
Left this trial due to adverse events	0% (0)	3% (3)	1% (1)

What serious adverse events did participants have?

During this trial, no participants reported serious adverse events and no one died.

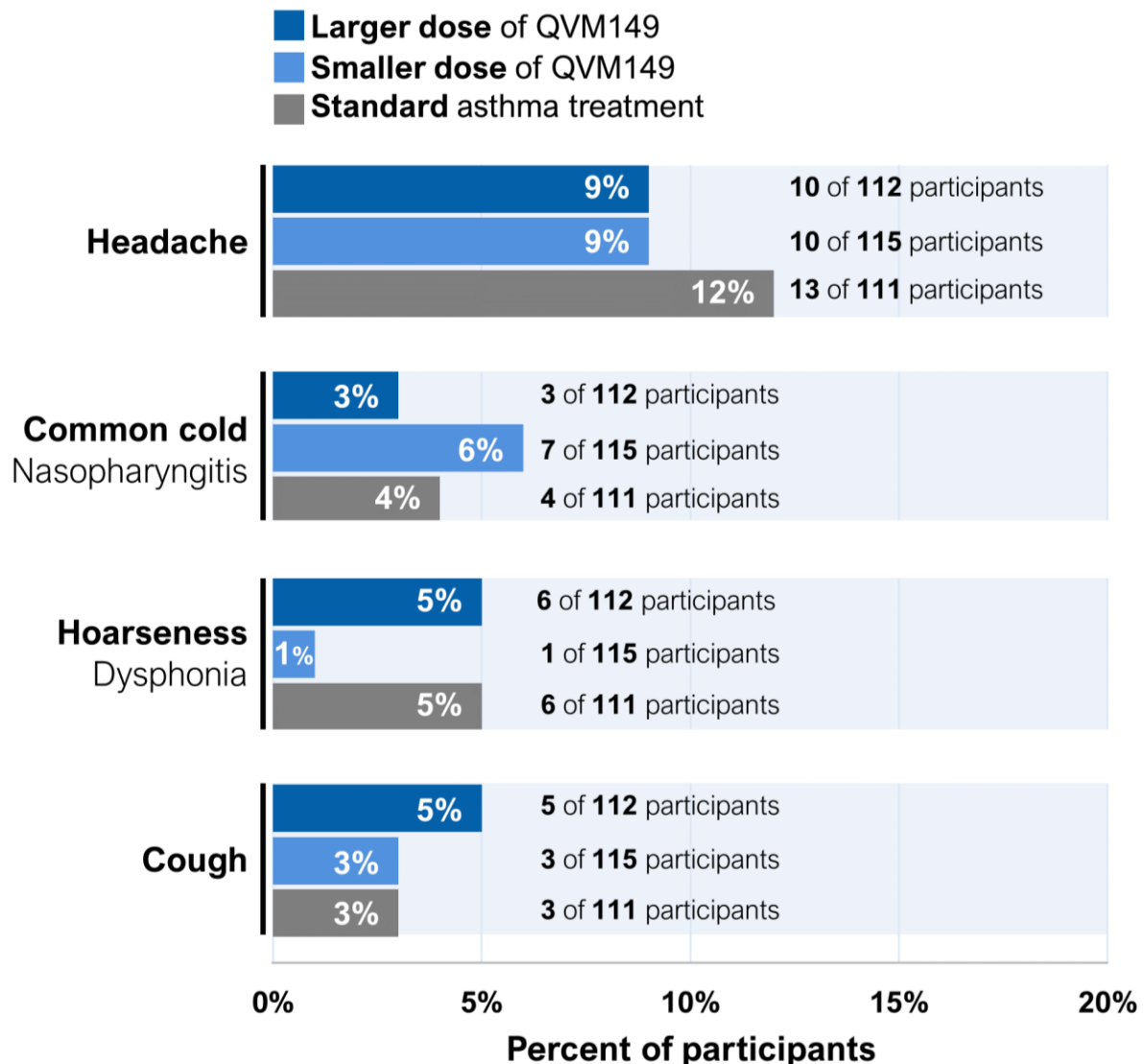
What types of adverse events did participants have?

Most participants reported medical problems or adverse events that were not serious. This summary reports adverse events that happened in 5% or more of participants. There were other adverse events that happened in fewer participants.



For more information about the adverse events reported by participants in this trial, visit novctrd.com. Use trial number **CQVM149B2208** to find the scientific summary.

Types of adverse events participants had



What was learned from this trial?

This trial helped to learn about the effects and safety of QVM149. The participants could breathe easier after they took either dose of QVM149 compared to after they took the standard asthma treatment. The clinical trial team concluded there was no meaningful difference in the safety of QVM149 compared to the standard asthma treatment.



The results presented here are for one clinical 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 asthma. This summary shows only the main results from this trial. Other trials may provide new information or different results.

Additional information about the treatments

What medicines were in a dose of each treatment?

The amounts below show the micrograms (μg) of the medicines in one dose of each treatment.

The **larger dose of QVM149** had:

- 150 μg (micrograms) indacaterol
- 50 μg glycopyrronium
- 160 μg mometasone

The **smaller dose of QVM149** had:

- 150 μg indacaterol
- 50 μg glycopyrronium
- 80 μg mometasone

The **standard asthma treatment** had:

- 50 μg salmeterol xinafoate
- 500 μg fluticasone propionate

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 trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on “**Clinical trial results and 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. Click on “**Search by study number**” at the bottom left of the page
5. Type “**CQVM149B2208**” 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 where you took part in this clinical trial.

This clinical trial was registered on the following websites:

- ClinicalTrials.gov – <https://clinicaltrials.gov>
To find this trial, type **CQVM149B2208** in the **Other terms** search box
- European Union Clinical Trials Register –
<https://www.clinicaltrialsregister.eu/ctr-search>
To find this trial, type **CQVM149B2208** in the search box

Full trial title:

A randomized, double-blind, double-dummy, active-controlled, 3-period complete cross-over study to assess the bronchodilator effect and safety of two doses of QVM149 compared to a fixed dose combination of salmeterol/fluticasone in patients with asthma

If more clinical trials are planned, they will appear on the public websites listed above. When there, search for **QVM149**.

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.



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

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