NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the effect and safety of QMF149 compared to mometasone furoate for adults and adolescents with poorly controlled asthma

Protocol number: CQVM149B2303

Thank You!

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. Thank you for taking part in this trial for the drug QMF149. You helped researchers learn more about how the effects and safety of QMF149.

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.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings. Researchers and health authorities, such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe, 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.

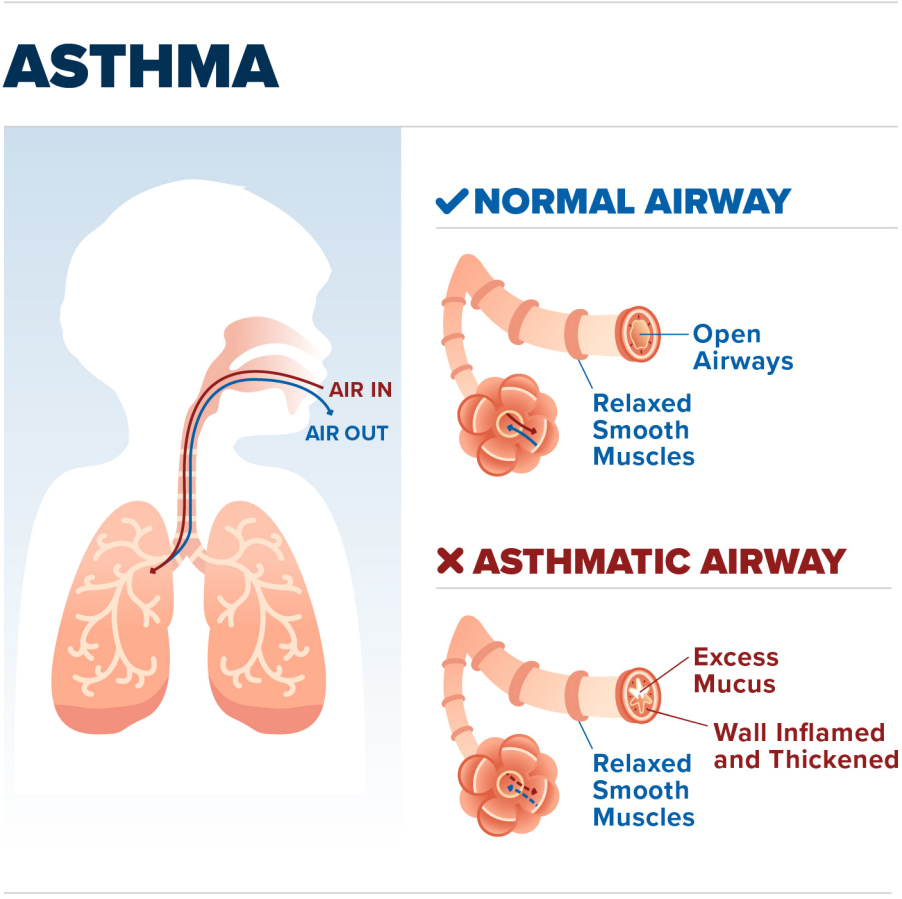
How long was this trial?

This trial was designed so that a participant could receive their assigned treatment for 12 weeks. The trial started in January 2017 and ended in November 2018.

The researchers completed this trial as planned. When the trial ended, the researchers collected information on the trial treatments (QMF149 and mometasone furoate) and created a report of the trial results. This summary is based on that report.

Why was the research needed?

Asthma is a condition that affects the lungs. The disease narrows the airways that carry and deliver oxygen into the lungs. This narrowing of the airways can make it hard to breathe. Researchers were looking for a better treatment to improve lung function and asthma symptom control for patients with poorly controlled asthma which is not completely improved by their current inhaled treatments.



Asthma, especially if it isn't properly controlled, can cause some of the following symptoms at different times of the day:

- inflammation (swelling) in the lungs
- chest tightness
- wheezing
- coughing

There is currently no known cure for asthma, but there are treatments available that can help manage symptoms.

QMF149 is an investigational drug that combines a long acting bronchodilator (a beta agonist [LABA]), which helps relax the airways of the lungs and a steroid medication, which helps reduce inflammation. As a result, this combination can improve asthma symptoms.

In this trial, researchers included participants who had already taken other inhaled asthma steroid medicines but still had asthma symptoms that were not improving. Researchers wanted to find out if giving QMF149 and a steroid medication to participants would improve their lung function and control asthma symptoms better than a standard inhaled steroid treatment alone.

Trial drugs

The drugs given in this trial were:

- **QMF149**, an investigational therapy made of a combination of indacaterol acetate and mometasone furoate that was being studied for the treatment of patients with poorly controlled asthma. QMF149 was taken once daily via inhaler.
- **Mometasone furoate**, also known as inhaled corticosteroid (ICS), is an anti-inflammatory steroid drug that is used for the treatment of asthma attacks. Mometasone furoate was taken once daily via inhaler.

All participants had poorly controlled asthma despite taking an asthma inhalation treatment with a low dose of ICS, with or without LABA, for at least 1 month before entering the trial.

Participants were given inhalers of salbutamol, also known as albuterol, to use as needed when their asthma symptoms got worse. This medicine is known as a "rescue" medicine.

Trial purpose

In this trial, researchers compared the results of all participants after 12 weeks of treatment with either QMF149 or mometasone furoate.

The key question the researchers wanted to answer in this trial was:

- How much more air could participants breathe out in one second at the end of 12 weeks of treatment compared with the start of the trial?

The other question researchers wanted to answer in this trial was:

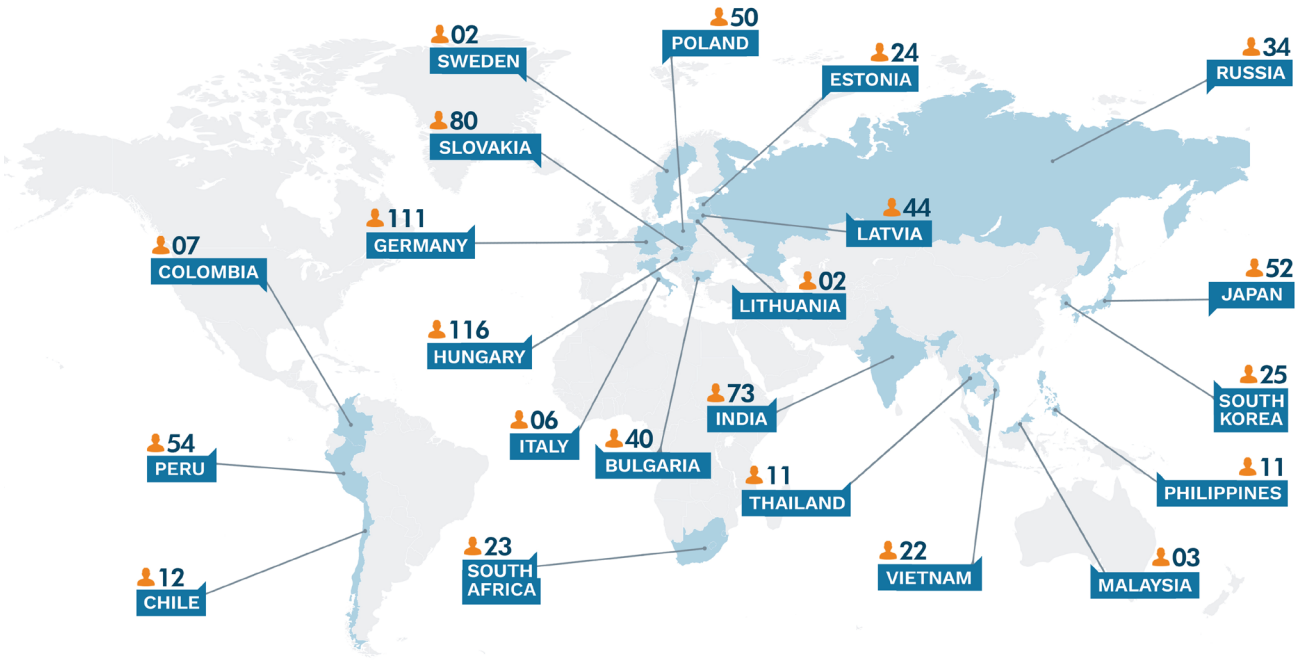
- How much did control of asthma symptoms improve for participants at the end of 12 weeks of treatment compared with the start of the trial?

Who was in this trial?

Participants could take part in this trial if they:

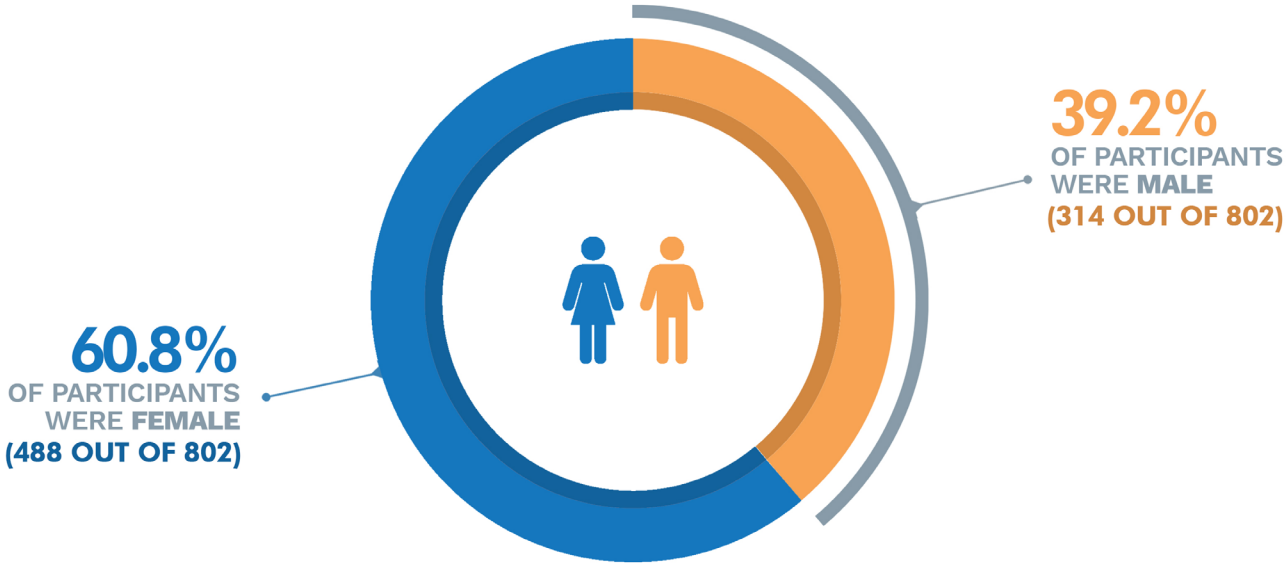
- were 12 years to 75 years of age and had a diagnosis of asthma at least 3 months before they entered the trial;
- were experiencing poorly controlled asthma symptoms despite previous treatment with asthma medication at a stable dose for at least 1 month before they entered the trial;
- did not have a history of chronic lung diseases other than asthma, or any other serious medical condition which could interfere with the study results.

A total of 802 participants from 22 countries participated in this trial.



The average age of participants in this trial was 45.6 years. The age of the participants ranged from 12 to 75 years, with a total of 8% of patients (64 out of 802) between 12 and 17 years; 78.6% of patients (630 out of 802) between 18 and 64 years; and 13.5% of patients (108 out of 802) with 65 years or older.

A total of 60.8% of the trial participants, 488 out of 802, were female. A total of 65.7% of participants (527 out of 802) were White, 24.8% of participants (199 out of 802) were Asian, 0.7% of participants (6 out of 802) were Black or African American, and 8.7% of participants (70 out of 802) were of other ethnicities.



What kind of trial was this?

This trial had both an open-label run-in period and a double-blinded treatment period. The run-in period was directly prior to receiving study treatment. All participants in the run-in period received twice-daily fluticasone propionate, an anti-inflammatory steroid drug. The run-in period was “open-label”, which meant that the participants, trial doctors, and trial staff knew that participants were receiving fluticasone propionate. The treatment period was “double-blinded”, which meant that neither the participants, trial doctors, nor the trial staff knew who received QMF149 or mometasone furoate.

What happened during this trial?

Participants went through a screening period that lasted up to 2 weeks to confirm that they could take part in the trial. Participants who qualified then entered the run-in period of the trial, wherein they were given open-label fluticasone propionate.

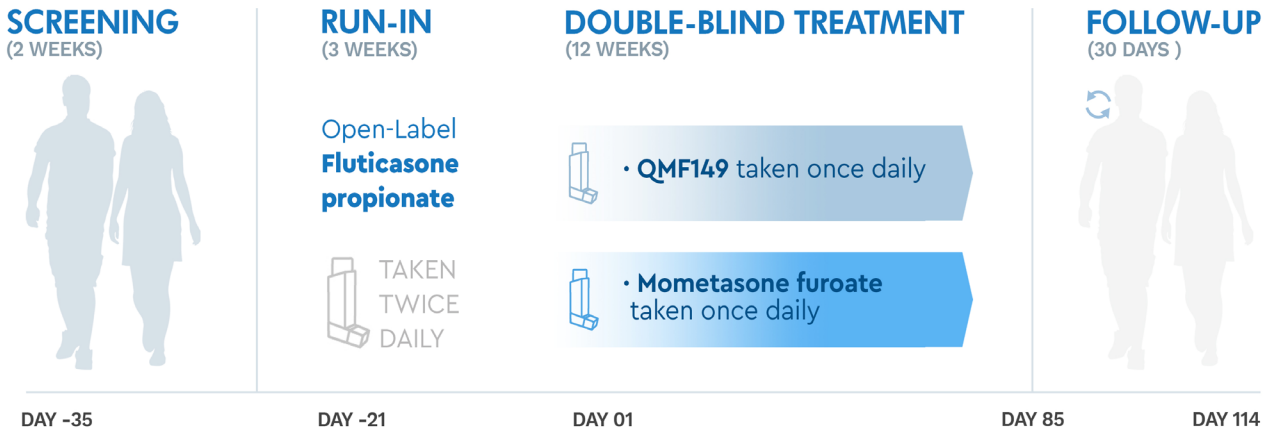
Researchers measured participants’ lung function throughout the trial with a lung function test. The lung function test measured how much air participants could forcefully breathe out of their lungs in one second into a machine that measures air force. This helped researchers learn about how severe the participants’ asthma was. Researchers also measured participants’ control of asthma symptoms using the Asthma Control Questionnaire-7 (ACQ-7). This questionnaire was given to participants to assess improvements in asthma control, such as positive changes in symptoms and reduced inhaler use.

The results recorded at the start of the trial were later used as the baseline to which researchers compared after-treatment results.

After the run-in period, participants were randomly (by chance) put into 2 groups. This process is called randomization. The participants were to receive either:

- **QMF149** taken via inhaler once a day (150/80 micrograms [µg])
- **Mometasone furoate** taken via inhaler once a day (200 µg)

If needed, participants could also use rescue medication for worsening asthma symptoms during the trial.



During the 12-week treatment period, participants visited their clinic every 4 weeks. Researchers compared the change in lung function and asthma symptom control at the start of the trial and at the end of Week 12 to see the effect of treatment.

Researchers also tracked the participants' health throughout the trial. Participants were contacted by telephone 30 days after their last dose of treatment for a follow-up.

What were the key results of this trial?

This is a summary of the average results for all participants in different 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. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How much more air could participants breathe out in one second at the end of 12 weeks of treatment compared with the start of the trial?

Researchers examined changes in lung function during the trial by measuring how much air participants were able to forcefully breathe out from their lungs in one second. Participants treated with QMF149 showed a significantly greater increase in the amount of air breathed out in one second after 12 weeks when compared to participants treated with mometasone furoate.

What were the other results of this trial?

Researchers also wanted to know the answer to the following question after 12 weeks of treatment.

How much did control of asthma symptoms improve for participants at the end of 12 weeks of treatment compared with the start of the trial?

Researchers measured participant's control of asthma symptoms with a questionnaire. Participants treated with QMF149 showed significantly more control of asthma symptoms after 12 weeks compared to participants treated with mometasone furoate.

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

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

An adverse event is an unwanted sign, 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.

How many participants had adverse events?

In this trial, 128 out of 396 participants (32.3%) in the QMF149 group and 153 out of 399 participants (38.3%) in the mometasone furoate group reported at least 1 adverse event. None of the participants died during the treatment period.

Number of Participants (%) with Adverse Events

	QMF149 (Out of 396 participants)	Mometasone furoate (Out of 399 participants)
At least 1 adverse event	128 (32.3%)	153 (38.3%)
At least 1 serious adverse event	5 (1.3%)	7 (1.8%)
Stopped drug due to adverse event	4 (1.0%)	8 (2.0%)

What was the most common non-serious adverse event?

Asthma attack was the most common non-serious adverse event that happened in at least 10 out of 100 (10%) of participants in either treatment group.

For a full list of the non-serious adverse events that occurred in this trial, please visit the websites listed at the end of this summary.

Number of Participants (%) With Most Common Non-Serious Adverse Event

	QMF149 (Out of 396 participants)	Mometasone furoate (Out of 399 participants)
Asthma attack	20 (5.1%)	60 (15.0%)

What was the most common serious adverse event?

The most common serious adverse event was bronchitis.

For a full list of the serious adverse events that occurred in this trial, please visit the websites listed at the end of this summary.

Number of Participants (%) With Most Common Serious Adverse Event

	QMF149 (Out of 396 participants)	Mometasone furoate (Out of 399 participants)
Bronchitis	0 (0%)	2 (0.5%)

How many participants stopped trial drug due to adverse events?

During the trial, 1.0% (4 out of 396) of participants in the QMF149 group and 2.0% (8 out of 399) of participants in the mometasone furoate group stopped their trial treatment early due to adverse events such as asthma attack, abdominal pain, cough, nausea, bronchitis, tonsillitis, enteritis (inflammation of the intestines), excessive sweating, trouble swallowing, and speaking difficulties. Ankle, fibula, and tibia fractures were reported in 3 participants in the mometasone furoate group.

How was this trial useful?

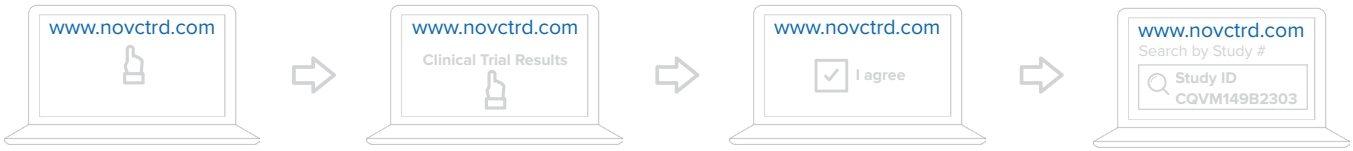
This trial helped researchers learn about how QMF149, given once a day, affects lung function and asthma control in adults and adolescents with asthma that is not completely controlled by currently available treatments.

Treatment with QMF149 showed greater improvement in lung function when compared to treatment with mometasone furoate. Participants who received QMF149 also experienced more improvement in the control of their asthma symptoms compared with participants who received mometasone furoate. The overall rate of adverse events was lower in participants who received QMF149.

This clinical trial was used to support approval for QMF149 in several countries globally, including the European Union, Canada, and Japan. Please remember, this summary only shows the results of a single clinical trial. 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 NCT02892344 in the search field.
- https://www.clinicaltrialsregister.eu/ctr-search/search Use the EudraCT identifier 2016-000472-22 in the search field.

Full clinical trial title: A Multi-center, Randomized, 12-week Treatment, Doubleblind Study to Assess the Efficacy and Safety of QMF149 (150/80 Microgram) Compared With MF Twisthaler® (200 Microgram) in Adult and Adolescent Patients With Asthma

THANK YOU

Thank you for taking part in this trial. As a clinical trial participant, you belong to a large community of people 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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