NOVARTIS

Clinical Trial Results Summary

A trial to learn about the effects and safety of QMF149 compared with mometasone furoate in adults and adolescents with asthma

Protocol number: CQVM149B2303

Thank You!

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

Novartis supported this trial and we believe it is important to share what we have learned from this trial with the participants and the public. As a clinical trial participant, you belong to a large community of people around the world. Your contribution to medicine and healthcare is very important and we are truly thankful for it.

This summary only shows the results of one clinical trial. Other clinical trials may have different results. 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 many clinical trials around the world to push medical science and healthcare forward. If you have any questions about these trial results, please talk to the doctor or staff at your trial clinic.

Glosary

Airways
the tubes that carry air into and out of the lungs

Clinical trial
a research study to learn about new drugs

Double-blinded
a study in which neither the participants nor the researchers know which participant takes which drug

Lung function
the ability of the lungs to bring in air and pass oxygen into the blood

Mucus
a sticky, gel-like substance that lines the lungs, throat, mouth, nose, and sinuses

Open-label
a study in which both the participants and the researchers know which participant takes which drug

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

Rescue medication
a fast-acting medication used to ease asthma symptoms right away

Researchers
people who conduct experiments; in this trial, these include the clinic doctor and the trial staff

Run-in period
the period between screening and randomization, during which all candidates receive the same medication – used to exclude candidates who experience health issues or don't follow the instructions

Swelling (also called inflammation)
an increase in the size or a change in the shape of a body part because of irritation

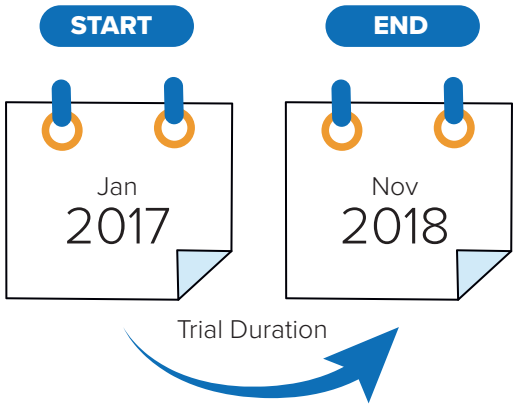
Symptom
a problem a person feels that may be a sign of a health condition or medical problem

Trial drug
a drug that researchers are studying in a clinical trial

How long was this trial?

Participants took the trial drug for 12 weeks, but the study started in January 2017 and ended in November 2018. This is because the participants started and stopped the trial at different times.

Our researchers completed this trial as planned. After the trial ended, they studied the information collected from the trial and made a report of the results. This is a summary of that report.



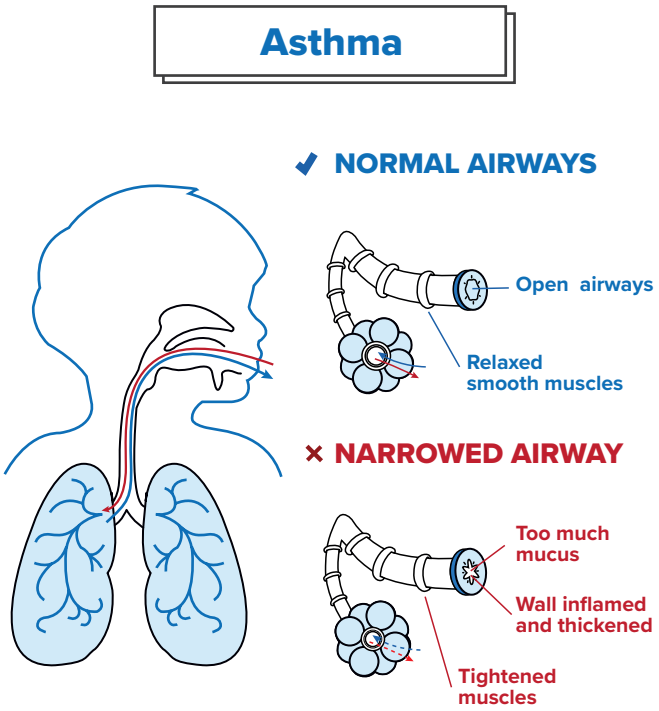
Why was the research needed?

In people with asthma, the airways in the lungs are swollen, narrower, and filled with mucus. This lets less oxygen into the lungs, making it hard to breathe.

At this time, there is no cure for asthma, but there are treatments that can help control the symptoms.

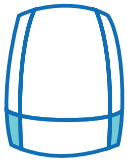
In this trial, our researchers were looking for a better way to treat asthma in people who are already taking asthma medications but their symptoms are not completely controlled. They wanted to see how well QMF149 could help control the asthma symptoms compared with mometasone furoate.

Some asthma symptoms are:
- swelling (inflammation) in the lungs
- chest tightness
- wheezing (a whistling sound while breathing)
- coughing



Trial drugs

Participants took one of the two treatments below during the treatment period of this trial:



QMF149, the inhaled drug that researchers were studying for the treatment of uncontrolled asthma. QMF149 is a combination of two medications: indacaterol acetate, which relaxes the tightened muscles of the lung airways; and mometasone furoate, a steroid medication that helps bring down the swelling in the airways of the lungs.

Mometasone furoate, a standard inhaled steroid medication that is commonly used to help bring down the swelling in the airways of the lungs.

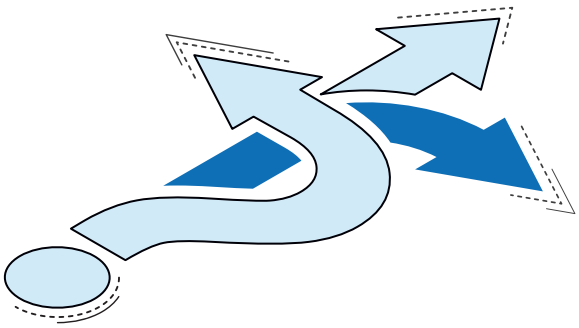
In addition, during the run-in period all participants took:

Fluticasone propionate, an inhaled steroid medication that treats asthma symptoms.

Participants also were given a rescue medication called **salbutamol,** also known as albuterol, before the trial started. This medication helps control the asthma symptoms right away, when needed.

What was the trial purpose?

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



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

• How much more air could participants on QMF149 or mometasone furoate 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:

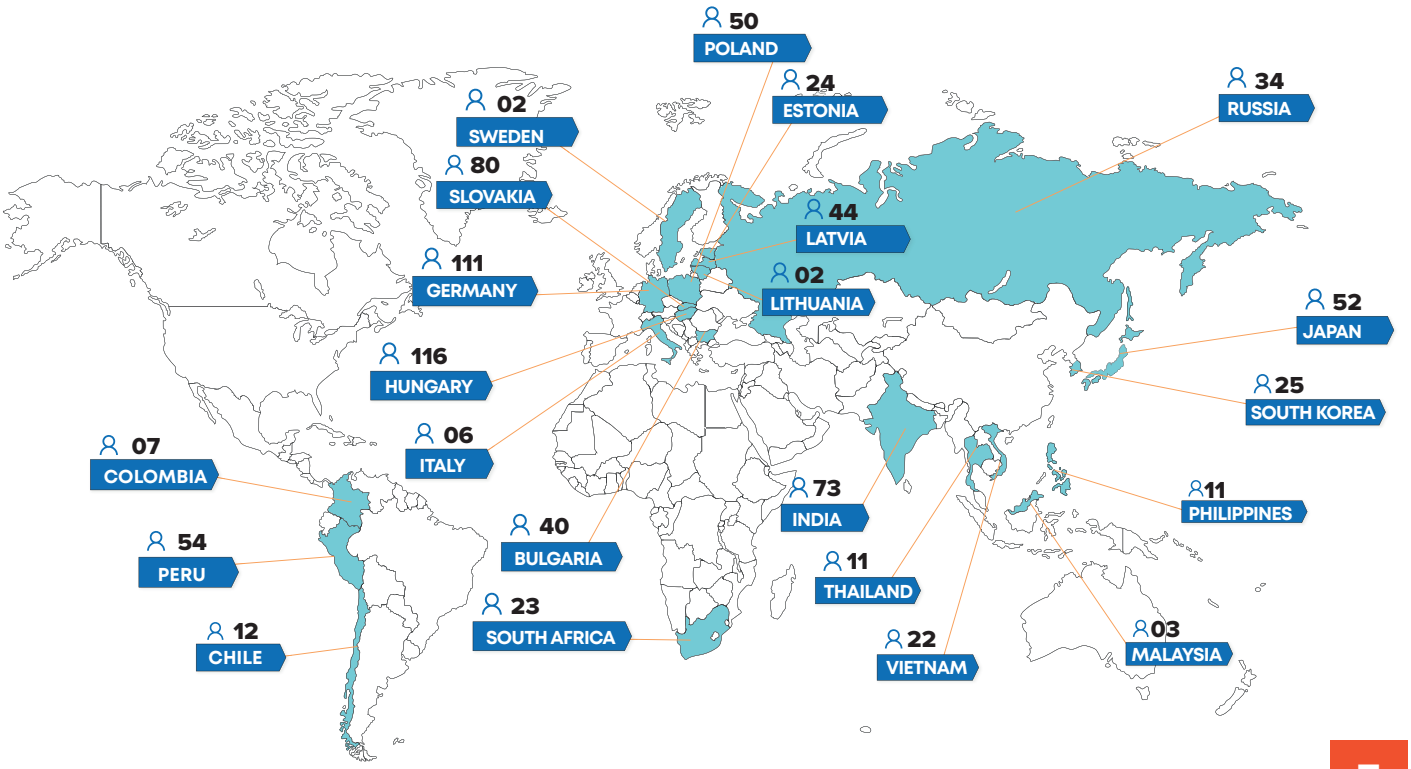
• How much did QMF149 or mometasone furoate help control asthma symptoms in participants at the end of 12 weeks of treatment, compared with the start of the trial?

Who took part in this trial?

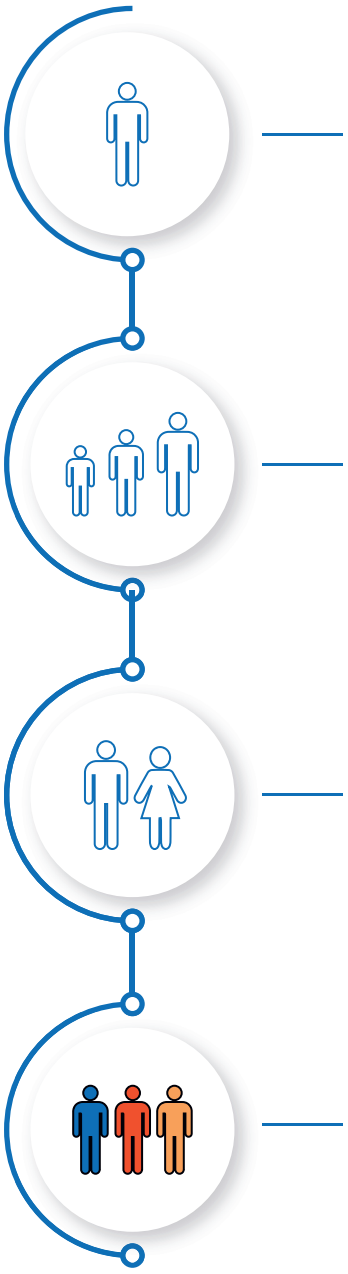
To answer the questions in this trial, we asked for the help of people like you who had asthma. Participants could take part in the trial if they:

- were 12 years to 75 years of age and had asthma, confirmed by the doctor, for at least 3 months before they started the trial,
- were already using inhaled asthma medicines with steroids, but still had asthma symptoms that were not completely controlled, for at least 1 month before they started the trial; and
- did not have a history of any other long-term lung condition besides asthma, or any other important medical condition that could affect the trial results.

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



Breakdown of the participants:



Average age	Range
45.6 years	12 - 75 years

12 – 17 years	18 – 64 years	65 years or older
8.0% (64 out of 802)	78.6% (630 out of 802)	13.5% (108 out of 802)

Men	Women
39.2% (314 out of 802)	60.8% (488 out of 802)

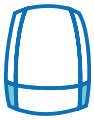
White	Asian	Black or African American	Other
65.7% (527 out of 802)	24.8% (199 out of 802)	0.7% (6 out of 802)	8.7% (70 out of 802)

What happened during this trial?

Screening period: Before treatment started, our researchers did health tests to make sure the participants could take part in the trial. This part lasted up to 2 weeks.

Run-in period (open-label): All participants who passed the screening period, entered the run-in period, when they took fluticasone propionate twice daily for 3 weeks. This helped the researchers decide which participants were suitable to continue in the trial.

Treatment period (double blinded): After the run-in period, the researchers used a computer program to randomly (by chance) put each participant into 1 of the 2 treatment groups to take either:



QMF149 (150/80 micrograms [µg]) once daily using a special inhaler + mometasone furoate placebo, or

Mometasone furoate (200 µg) once a day using a special inhaler + QMF149 placebo

This is called randomization and helps make sure that comparing the results of the treatments is as fair as possible.
If needed, participants could also use the rescue medication, salbutamol (also known as albuterol).

The treatment period lasted 12 weeks. At the end of the 12 weeks, researchers recorded the results and compared them with the results from the start of the trial to see how the treatment changed the lung function.

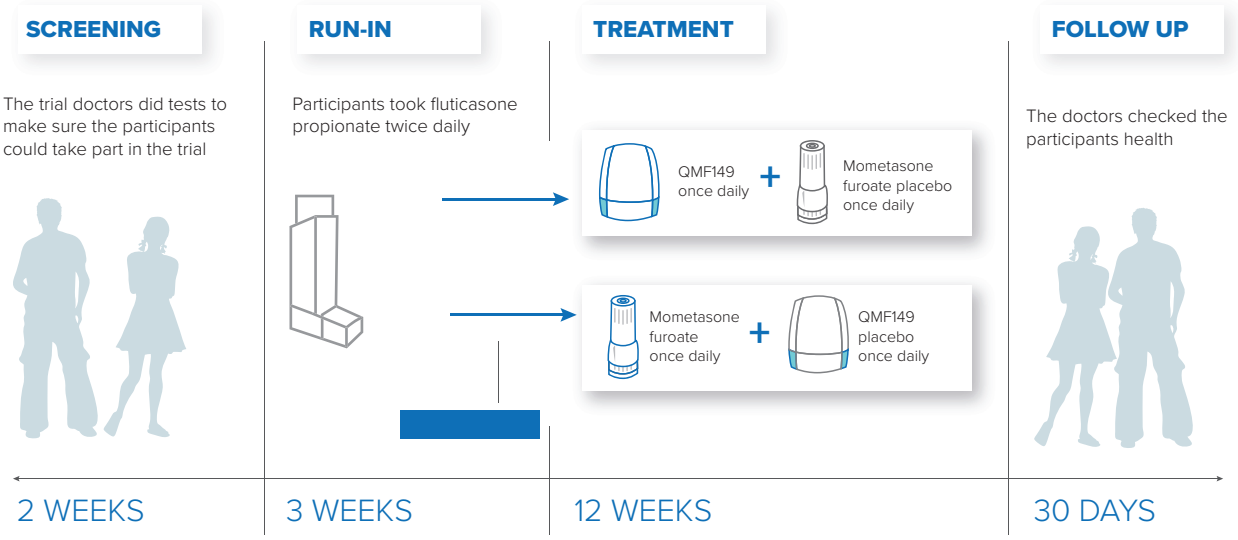
During the trial, researchers measured how well each participant's lungs worked (the lung function test). They did this by measuring how much air each of you could forcefully breathe out of your lungs in one second into a machine that measures air force. This helped researchers know how severe each participant's asthma was.

Researchers also asked the participants to answer a set of questions called an Asthma Control Questionnaire-7 (ACQ-7). Your answers helped researchers measure how well your asthma symptoms were controlled, for example researchers could learn if your asthma symptoms were getting better, and if you needed to take less puffs of your rescue medication.

Researchers tracked the health of participants during the trial.

Follow-up: Researchers called the participants 30 days after their last dose of treatment and asked them to come in for a follow-up. At this visit, the participants' health was checked again.

The chart below is a summary of what happened in this trial.

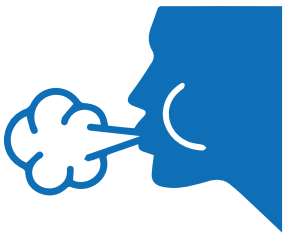


What were the key results of this trial?

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 amount of air participants were able to forcefully breathe out in one second showed researchers the changes in lung function during the trial. If participants could breathe out more air it meant that their breathing was easier.

Participants who took QMF149 could breathe out significantly more air in one second after 12 weeks compared with participants who took mometasone furoate.



What were the other results of this trial?

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

To find this out, researchers measured participant's control of asthma symptoms using the Asthma Control Questionnaire-7 (ACQ-7).

Participants who took QMF149 showed significantly more control of asthma symptoms after 12 weeks compared with participants who took mometasone furoate.

What medical problems did the participants have during the trial?

An adverse event is an unwanted sign, symptom, or disease that participants have during a trial.

During a trial, we keep track of all adverse events that participants have, even if we don't think they are caused by the trial drug.

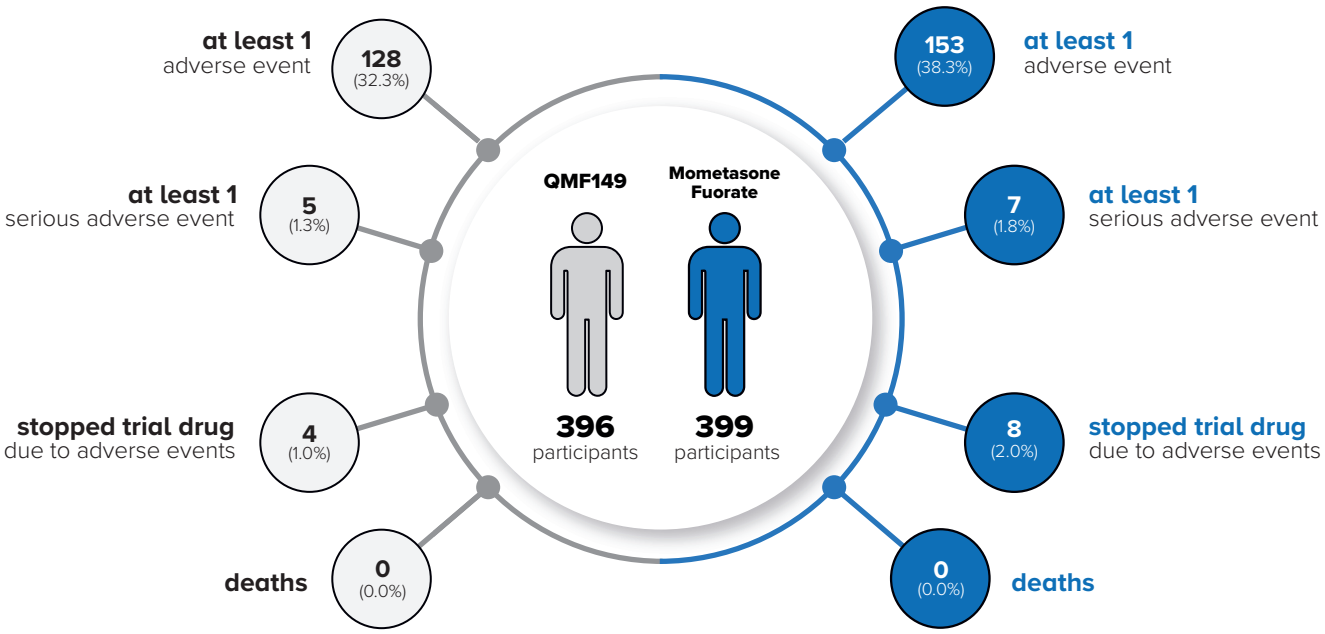
This is a summary of the adverse events that happened during this trial. You can find more information in the websites listed at the end of this summary.

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 this trial.

Number of Participants (%) With Adverse Events

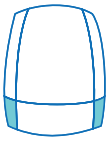


What was the most common non-serious adverse event?

Asthma attack was the most common non-serious adverse event that happened in at least 10 out of 100 (10%) of participants in either the QMF149 or the mometasone furoate group.

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

Ashtma Attack



QMF149
(Out of 396 participants)
20 (5.1%)

Vs

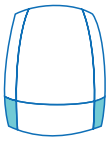
Mometasone furoate
(Out of 399 participants)
60 (15.0%)

What was the most common serious adverse event?

The most common serious adverse event was swelling of the lung airways (bronchitis).

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

Bronchitis



QMF149
(Out of 396 participants)
0 (0%)

Vs

Mometasone furoate
(Out of 399 participants)
2 (0.5%)

How was this trial useful?

In this trial, you helped researchers learn about the effect of QMF149, taken once daily, on the lung function and control of asthma symptoms in adults and adolescents with asthma that is not completely controlled by currently available treatments.

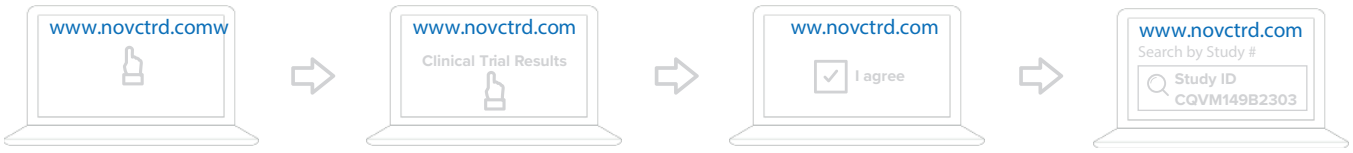
Researchers found that QMF149:

- was more effective than mometasone furoate to help the lungs function better.
- helped more than mometasone furoate to control asthma symptoms.
- caused overall less adverse events than mometasone furoate.

We used the results from this clinical trial to get approval for use of QMF149 in many countries around the world, including the European Union, Canada, and Japan.

Where can I learn more about this trial?

You can learn more about the results and adverse events in this trial on the Novartis Clinical Trial Results website (www.novctrd.com). Use Study identifier CQVM149B2303 in the search field.



You can also find more information about this trial on the websites below:

- 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, double-blind 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

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1-888-669-6682 (US); +41-61-324-1111 (EU);

www.novartisclinicaltrials.com

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 researches answer important health questions and test new medical treatments.