Clinical Trial Results Summary

A clinical trial to learn about the effect and safety of fevipiprant on lung function in people with uncontrolled asthma

Protocol number: CQAW039A2317

Thank You!

Novartis, the sponsor of this clinical trial, would like to thank you for taking part in this trial for the drug QAW039, also known as fevipiprant. You helped researchers learn more about how fevipiprant affects lung function in people with asthma whose symptoms are not completely controlled by the medicine they are already taking.

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, 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.

Glossary

Adverse events
medical problems that happen during clinical trials

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

Clinical trial
a research investigation in which people voluntarily participate to evaluate the effects and safety of new drugs

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

Fevipiprant
a drug being developed to decrease swelling of the airways in lungs and to treat asthma; it is taken orally

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

Rescue medicine
fast-acting medicine given to relieve asthma symptoms immediately

Researchers
someone who conducts experiments; in this trial, these include the hospital doctor and trial staff

Swelling
the body's response to injuries and infection; also called inflammation

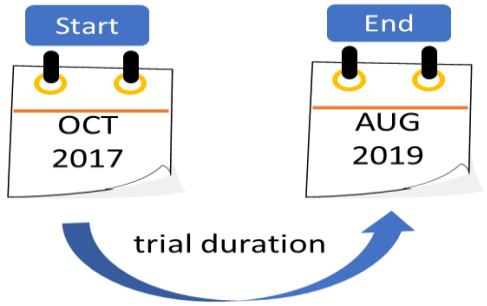
Standard-of-care
medicine that is usually taken by people for their asthma symptoms

Trial drug
drug being studied or researched in a clinical trial

Uncontrolled asthma
asthma with symptoms that cannot be managed, despite taking asthma medicines

White blood cells
the cells of the immune system that help fight infections by attacking bacteria, viruses, and germs that attack the human body

How long was this trial?



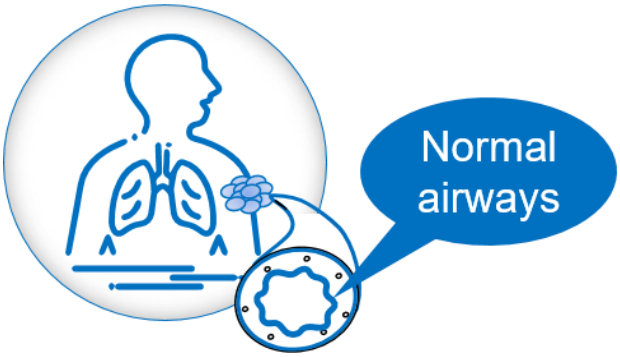
This trial was designed so that an individual participant could take part for about 4 months. The trial started in October 2017 and ended in August 2019.

The researchers completed this trial as planned. This summary is based on that report.

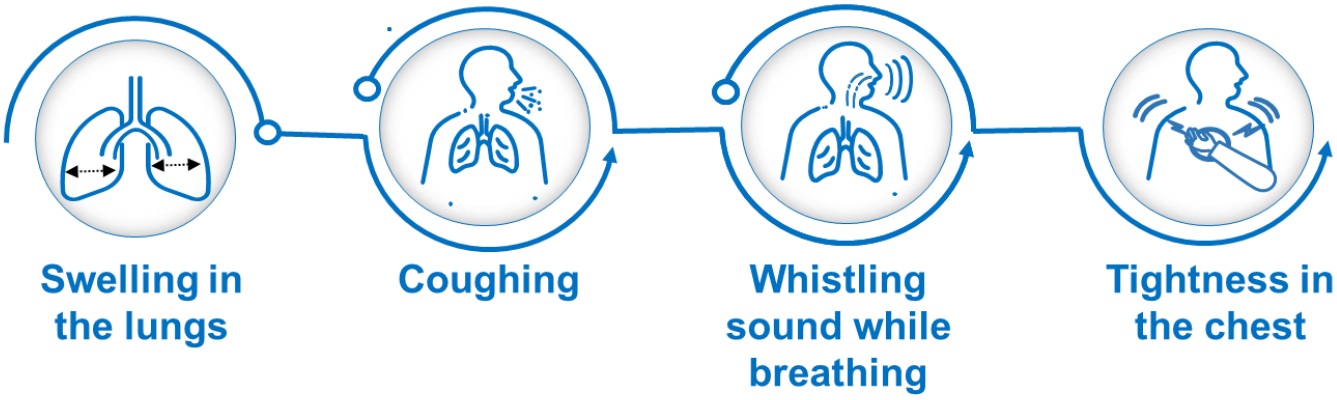
Why was the research needed?

Uncontrolled Asthma

Researchers were looking for a better way to treat asthma that is not completely controlled by currently available treatments. Asthma is a condition that narrows the airways that carry oxygen into the lungs, making it hard to breathe.



Symptoms of asthma:



Although there is no known cure for asthma, there are medicines available that can help manage the symptoms of asthma.

Usually in people with asthma, white blood cells move to the lungs and cause swelling, which can make it difficult to breathe. In this trial, fevipiprant is being studied to see if it can stop white blood cells from moving into the lungs. If so, this should decrease swelling in the lungs and improve asthma symptoms.

In this trial, researchers included participants who were already taking other medicine for asthma, but had asthma symptoms that were not improving. During the trial, participants were required to continue taking their regular asthma medicine. Researchers wanted to find out if giving fevipiprant to participants in addition to their regular asthma medicine would improve how much air they could forcefully breathe out of their lungs in one second.

Trial drugs

Fevipiprant (QAW039)

An investigational drug that was being studied for the treatment of uncontrolled asthma.

Placebo

Looked like the trial drug but *did not have any medicine* in it. Using a placebo helps researchers better understand the effect of a trial drug by making sure that the changes are not happening by chance.

In addition to one of the two treatments above, participants continued to take their regular asthma medicines. Additionally, participants received rescue asthma inhalers to take in case of increased asthma symptoms.

Trial purpose

In this trial, researchers compared the results of all participants after 12 weeks of treatment with either fevipiprant or placebo, when given along with their regular asthma medicine.

The main 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 questions researchers wanted to answer in this trial were:

- Were there fewer daytime asthma symptoms in participants taking fevipiprant compared with participants taking placebo?
- Was the number of puffs of rescue medicine used lower in participants taking fevipiprant compared with participants taking placebo?
- Did the quality of life of participants taking fevipiprant improve compared with participants taking placebo?

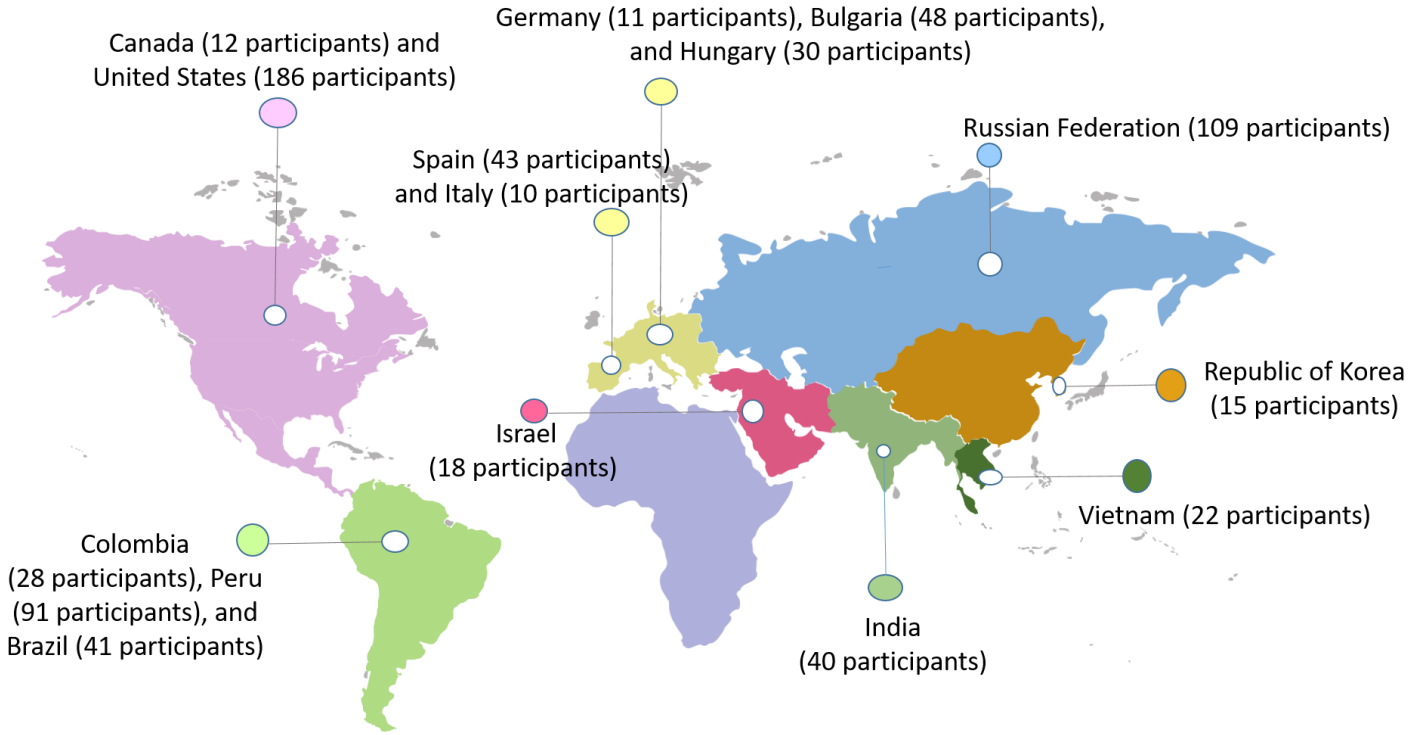
Who was in this trial?

The participants could take part in this trial if they:

- **were 12 years of age** or older **and** had **asthma for 6 months or more** before the trial started
- were already taking **other medicine** for asthma
- were already taking **at least 1 puff of rescue medicine** during 4 of the last 7 days of the placebo run-in period
- did not have **any heart problems or other serious conditions**

A total of 704 participants from 15 countries participated in this trial.

Total number of participants in each country



Out of the 704 participants, 2 participants were incorrectly entered into the trial and did not receive any treatment.

Average age
50 years
Range
12–84 years

12–17 years: 2%
(13 out of 702 participants)
18–64 years: 80%
(561 out of 702 participants)
65–84 years: 18%
(128 out of 702 participants)

Men: 38%
(268 out of 702 participants)
Women: 62%
(434 out of 702 participants)

What kind of trial was this?

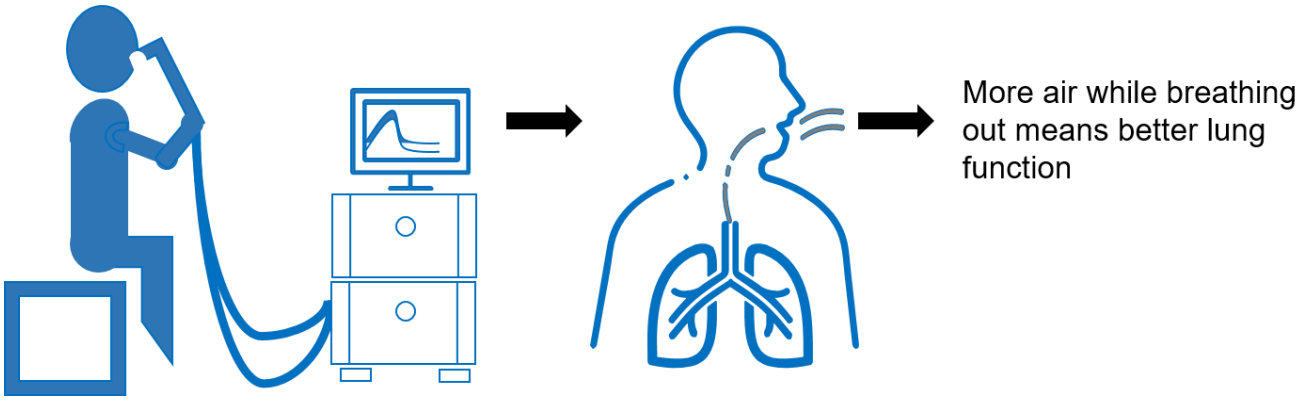
None of the trial participants, trial doctors, or trial staff knew what treatment participants were receiving.

- 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?

Participants went through a screening and placebo run-in period to confirm that they could take part in the trial. During these 2 periods, participants recorded their symptoms and all asthma medicines they were taking in their electronic diaries.

During the placebo run-in period, participants took placebo along with their regular asthma medicine daily. 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.

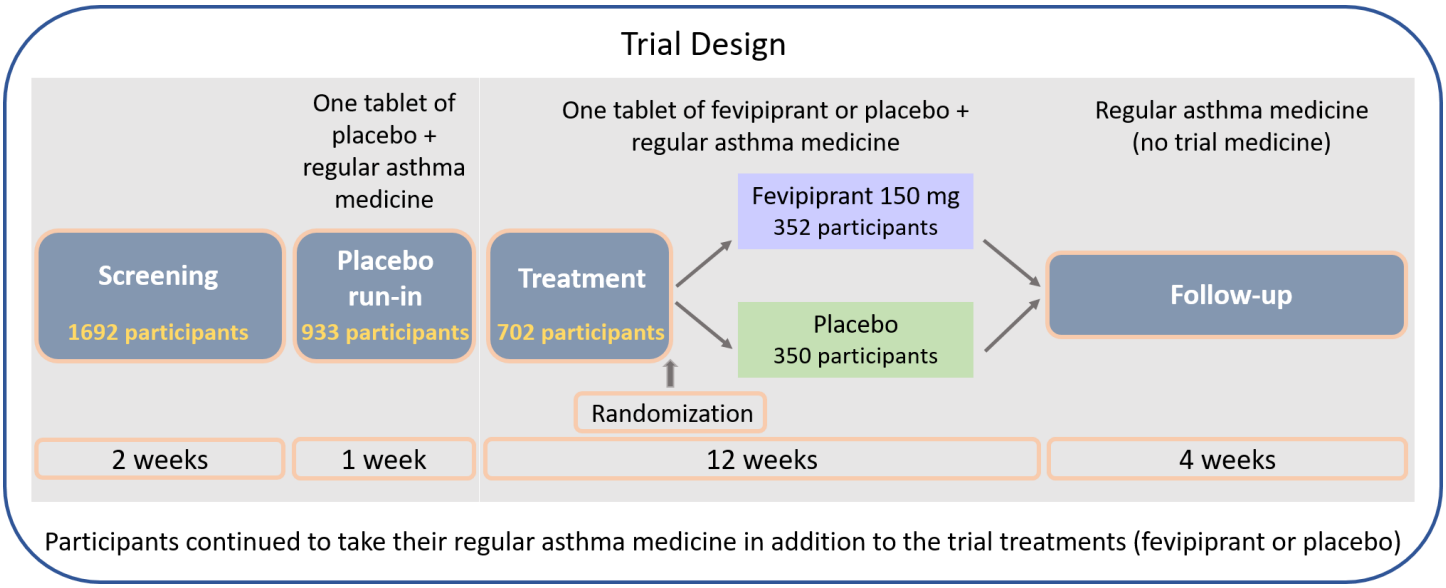


This helped researchers learn about how severe the participants' asthma was. The results recorded at the start of the trial were later used as the baseline to which researchers compared after-treatment results.

After the placebo run-in period, the participants were randomly put into 2 groups to receiver either:

- **Fevipiprant** as a tablet once a day, at a dose of 150 milligrams (mg)
- **Placebo** as a tablet once a day

This process is called randomization. Participants continued to take their regular asthma medicine throughout the trial, from screening until the end of the follow-up period. If needed, participants could also use the rescue medicine for asthma during the trial.



Researchers compared the change in the values of lung function tests at the start of the trial and at the end of Week 12 to see the effect of the treatment on lung function.

Researchers also tracked the participants' health throughout the trial. Participants returned to their trial site 4 weeks after their last dose of treatment for a follow-up visit. During the follow-up period, the participants were not given any trial treatment. However, participants continued to take their regular asthma medicine. At the follow-up visit, the participants' health was checked.

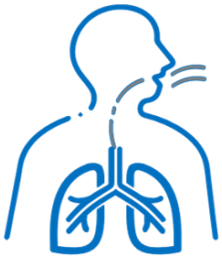
What were the key results of this trial?

This is a summary of the average 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. 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?

Fevipiprant + regular asthma medicine

Placebo + regular asthma medicine



increase of 126 mL of air from start of trial

increase of 157 mL of air from start of trial

The change in amount of air was *about the same* for participants in both groups, fevipiprant and placebo, when given along with regular asthma medicine.

What were the other results of this trial?

Researchers also wanted to know the answers to the following questions after 12 weeks of treatment.

Were there fewer daytime asthma symptoms in participants taking fevipiprant compared with participants taking placebo?

No difference was seen in the participants' daytime asthma symptom scores. These scores came from information recorded in the electronic diary twice a day.

Was the number of puffs of rescue medicine used lower in participants taking fevipiprant compared with participants taking placebo?

No difference was seen in the number of puffs of rescue medicine used between both groups. This information came from the number of puffs recorded in the electronic diary twice a day.

Did the quality of life of participants taking fevipiprant improve compared with participants taking placebo?

No difference was observed between the 2 groups in the improvement of quality of life after 12 weeks of treatment. Quality of life information came from the questionnaire that participants completed on the tablet at the site during the study.

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.

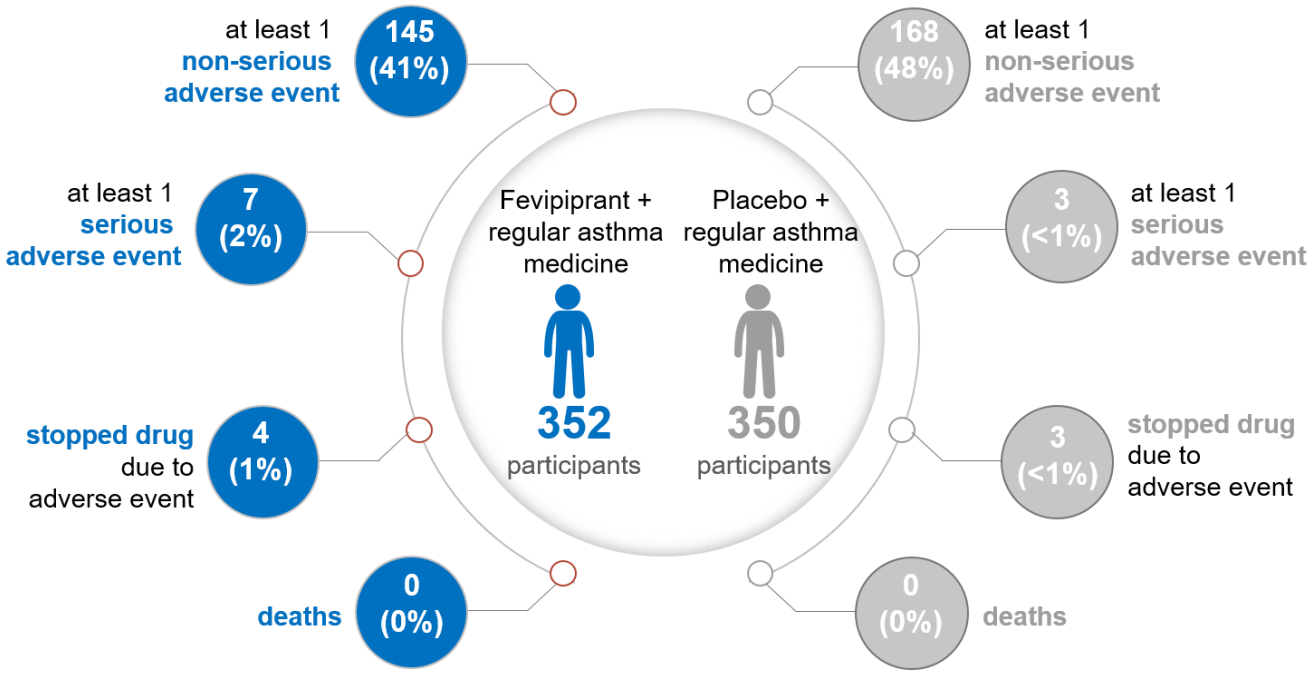
This section is a summary of the adverse events that happened during this trial. The websites listed at the end of this summary may have more information about all the adverse events that happened in this trial.

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.

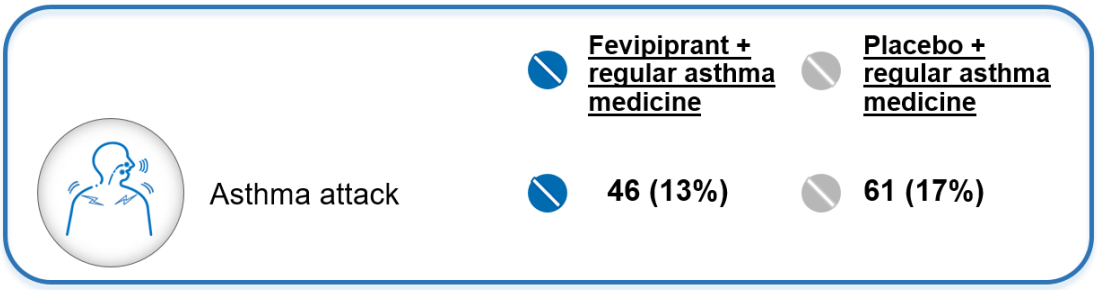
How many participants had adverse events?

In this trial, 145 out of 352 participants (41%) in the fevipiprant group and 168 out of 350 participants (48%) in the placebo group reported at least 1 adverse event.



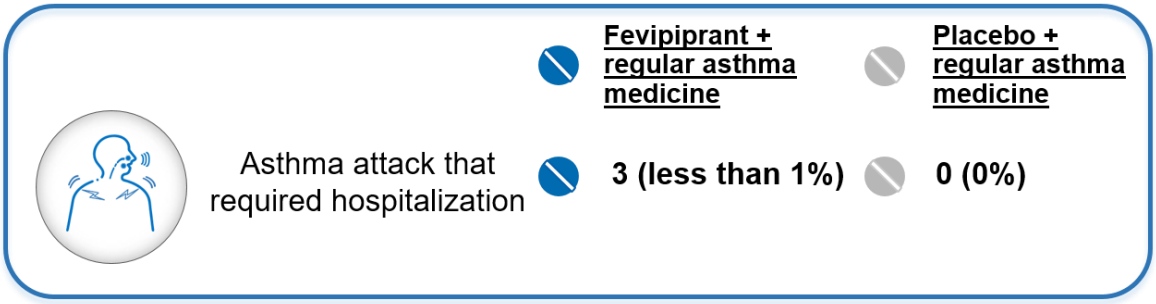
What was the most common non-serious adverse event?

The most common non-serious adverse event that happened in at least 10 out of 100 (10%) of the participants in either the fevipiprant or the placebo groups was asthma attack.



What was the most common serious adverse event?

The most common serious adverse event, which was reported by more than 2 participants in any group, was asthma attack that required hospitalization. There were no deaths reported during this trial.

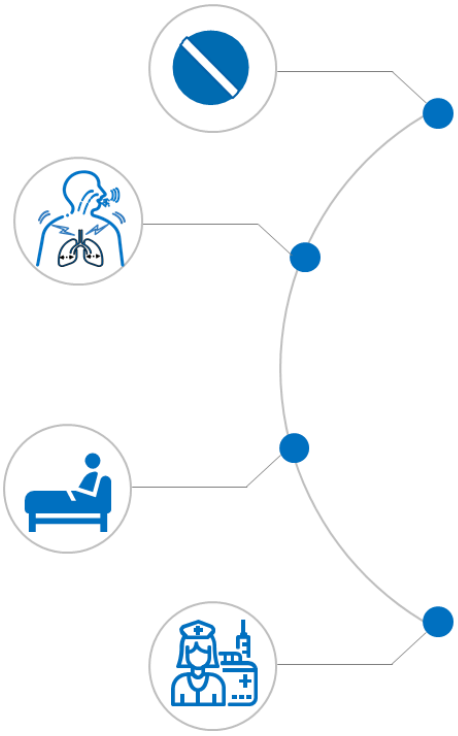


How many participants stopped trial drug due to adverse events?

Of the 352 participants receiving fevipiprant, 4 participants (1%) stopped treatment early due to adverse events such as cancer of the prostate, a lump in the ovary, asthma, rash, and cough associated with phlegm.

Of the 350 participants receiving placebo, 3 participants (less than 1%) stopped treatment early due to adverse events such as irregular and fast heartbeat, pain in the upper part of the stomach, liver damage, headache, runny nose, and irritation in the throat.

How was this trial useful?



This trial helped researchers learn about how the 150 mg dose of fevipiprant given once a day affects lung function in people with asthma that is not completely controlled by currently available treatments. Fevipiprant was not found to be more effective than placebo when taken in addition to regular asthma medicine. Both the fevipiprant and placebo groups also reported similar adverse events. Based on the results of this and other trials, the clinical research of fevipiprant for asthma was stopped.

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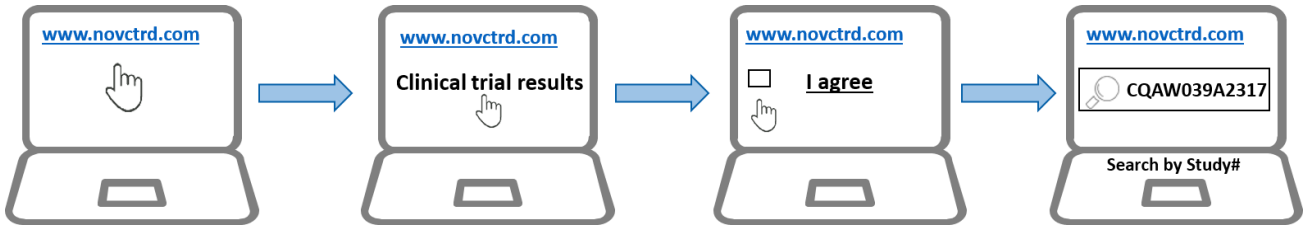
Where can I learn more about this trial?

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 NCT03226392 in the search field.
- https://www.clinicaltrialsregister.eu/ctr-search/search Use the EudraCT identifier 2017-001272-40 in the search field.

Full clinical trial title: A 12-week, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of QAW039 when added to standard-of-care asthma therapy in patients with uncontrolled 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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www.novartisclinicaltrials.com