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.

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. When the trial ended, the researchers collected information on the trial treatments (fevipiprant and placebo) when given along with regular asthma medicine and created a report of the trial results. This summary is based on that report.

Why was the research needed?

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.

This condition causes some of the following symptoms at varying times:

- inflammation in the lungs
- tightness in the chest
- a whistling sound while breathing
- coughing

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

Usually in people with asthma, white blood cells move to the lungs and cause inflammation, which can make it difficult to breathe. Fevipiprant is an investigational drug that works by stopping these blood cells from moving into the lungs. This decreases inflammation in the lungs and improves asthma symptoms.

In this trial, researchers included participants who were already taking other medicine for asthma, but still had 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 their lung function.

Researchers checked the lung function of participants by measuring how much air they could forcefully breathe out of their lungs in one second.

Trial drugs

The drugs given in this trial were:

- **Fevipiprant (QAW039),** an investigational drug that was being studied for the treatment of uncontrolled asthma.
- **Placebo,** which 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.

Participants continued to take their regular asthma medicine to improve symptoms. The most common asthma treatment taken by nearly 85% of the participants was a combination of 2 medicines: long-acting beta agonists (LABA) to help with breathing by relaxing the muscles of the lungs and inhaled corticosteroids (ICS) to reduce inflammation in the lungs.

Participants were also given inhalers of salbutamol, also known as albuterol, to use if needed when their asthma symptoms got worse. This medicine was known as “rescue” medicine.

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?

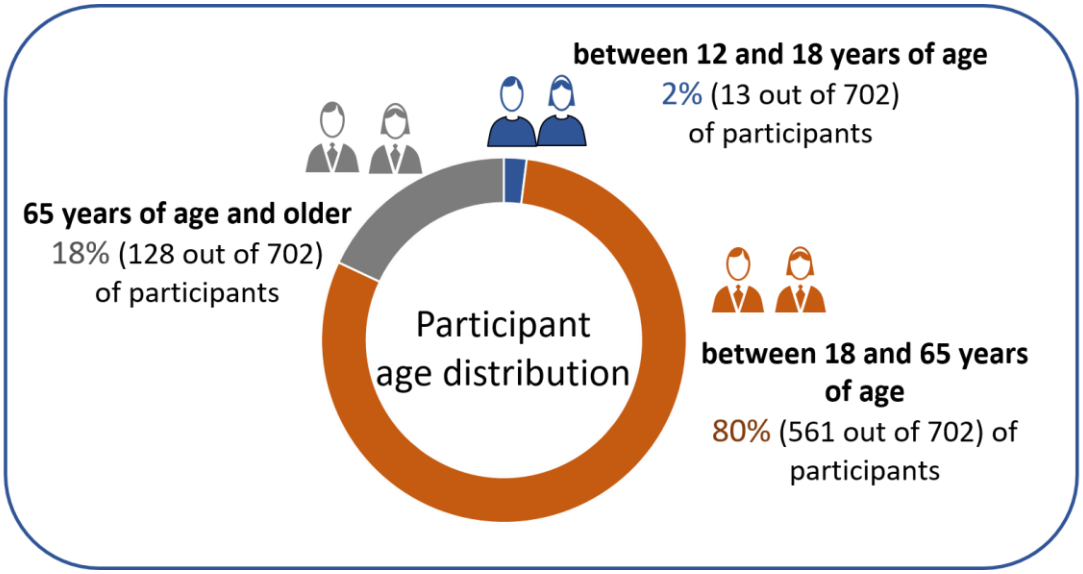
The participants could take part in this trial if they:

- were 12 years of age or older and had asthma for at least 6 months before they entered the trial;
- 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 medical conditions.

A total of 704 participants from 15 countries participated in this trial. However, 2 participants were incorrectly entered into the trial due to an error and did not receive any treatment, so the trial results are from 702 participants.

Total number of participants in each country

The average age of participants in this trial was 50 years. About 62% of the trial participants, or 434 out of 702, were female. Participants' age ranged from 12 years to 84 years.



What kind of trial was this?

This was a double-blind trial. This means that none of the 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?

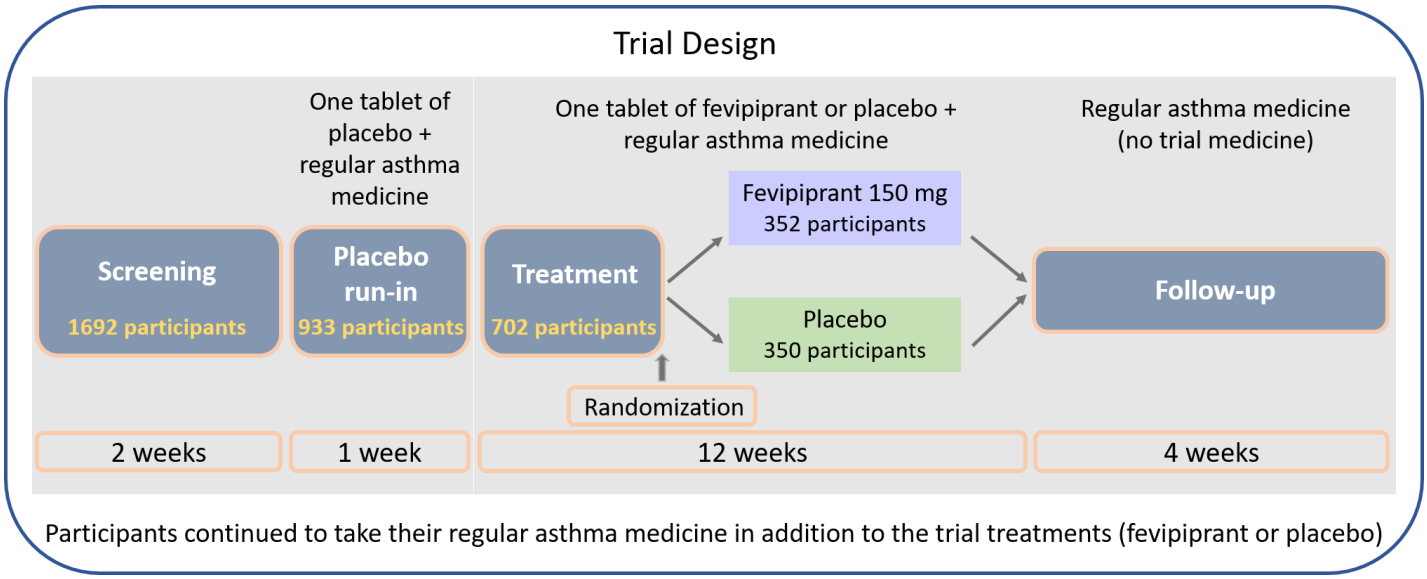
Participants went through a screening and placebo run-in period to confirm that they could take part in the trial. During these two periods, participants recorded their symptoms and all other asthma medicines they were taking in their electronic diaries.

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. This process is called randomization. The participants were to receive either:

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

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 worsening asthma symptoms 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.

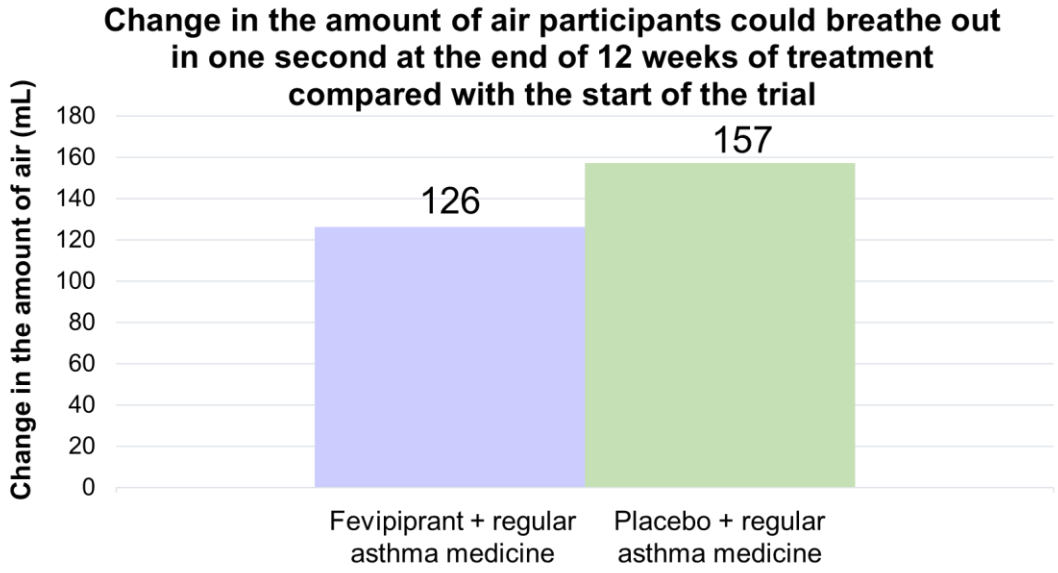
Researchers also tracked the participants' health throughout the trial. Participants returned to their trial site 4 weeks after their last dose of treatment for a follow-up visit. During the follow-up period, the participants were not given any trial treatment. However, participants continued to take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

The change in amount of air was about the same for participants in both the fevipiprant group and the placebo group. This means that fevipiprant did not control asthma symptoms more than placebo when both were given in addition to 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 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. There were no deaths reported during this trial.

Number of Participants (%) With Adverse Events

	Fevipiprant + regular asthma medicine (Out of 352 participants)	Placebo + regular asthma medicine (Out of 350 participants)
At least 1 adverse event	145 (41%)	168 (48%)
At least 1 serious adverse event	7 (2%)	3 (Less than 1%)
Stopped drug due to adverse event	4 (1%)	3 (Less than 1%)

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.

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

	Fevipiprant + regular asthma medicine (Out of 352 participants)	Placebo + regular asthma medicine (Out of 350 participants)
Asthma attack	46 (13%)	61 (17%)

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.

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

	Fevipiprant + regular asthma medicine (Out of 352 participants)	Placebo + regular asthma medicine (Out of 350 participants)
Asthma attack that required hospitalization	3 (less than 1%)	0 (0%)

How many participants stopped trial drug due to adverse events?

During the trial, 1% (4 out of 352) of participants stopped fevipiprant early due to adverse events such as cancer of the prostate, a lump in the ovary, worsening of asthma, rash, and cough associated with phlegm. Both rash and cough were reported by the same participant.

Less than 1% (3 out of 350) of participants stopped placebo early because of adverse events such as headache, runny nose, pain in the upper part of the stomach, irritation in the throat, irregular fast heartbeat, and abnormal liver-related laboratory test results. All events except for irregular heartbeat and abnormal laboratory test results were reported by the same participant.

How was this trial useful?

This trial helped researchers learn about how the 150 mg dose of fevipiprant given once a day affects the lung function of people with asthma that is not completely controlled by currently available treatments. Fevipiprant was not found to be more effective than placebo in this trial 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 fevipiprant trials, the clinical research of fevipiprant for asthma was stopped.

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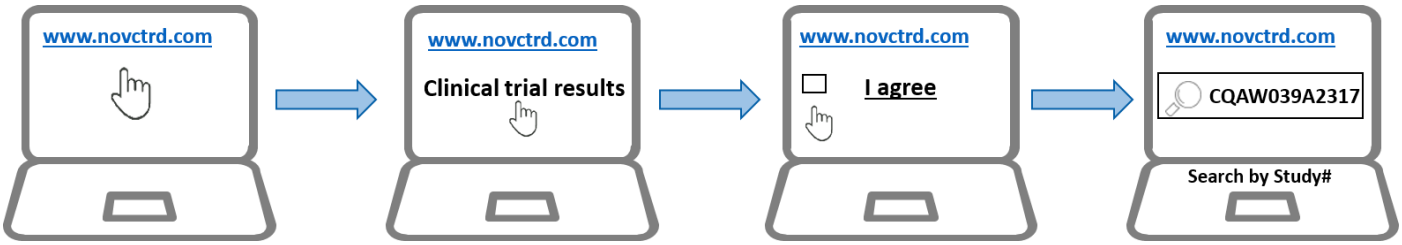
Where can I learn more about this trial?

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

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