NOVARTIS

Clinical Trial Results Summary

A clinical trial to find out the effects of fevipiprant on participants with nasal polyps and asthma

Protocol number: CQAW039A2322

Thank You!

Novartis sponsored this trial and believes it is important to share the results of the trial with you and the public. Thank you for taking part in this trial for the drug QAW039, also known as fevipiprant. You helped researchers learn more about how fevipiprant works in people with nasal polyps and asthma.

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 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 just over 5 months. The trial started in March 2019 and ended in June 2020. The entire duration, from enrolling the first participant to the last participant completing the trial, was about 1 year and 3 months.

The researchers completed this trial as planned. When the trial ended, the researchers collected information on the trial treatments, fevipiprant and placebo, and created a report of the trial results. This summary is based on that report.

Why was the research needed?

This trial was done to learn whether fevipiprant could shrink nasal polyps by reducing inflammation.

Researchers were looking for a better way to treat nasal polyps in people who also have asthma. Nasal polyposis (polyps) is a condition in which the inner lining of the nose develops nasal polyps. Nasal polyps are painless soft growths inside your nose that cause symptoms such as stuffy nose, runny nose, constant need to swallow (post-nasal drip), reduced sense of smell and, less commonly, facial pain. Asthma is a condition that narrows and inflames the airways that carry oxygen into the lungs, making it hard to breathe.

People affected with nasal polyps often have other conditions like asthma, cystic fibrosis and sensitivity to aspirin. Usually in people with asthma, white blood cells move to the lungs and airway tissues causing 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. Researchers believe that fevipiprant could also be a suitable treatment for nasal polyps.

Current treatments for nasal polyps include corticosteroid nasal sprays, also called nasal steroid sprays, or surgery. Corticosteroids are drugs that reduce inflammation.

Trial drugs

The drugs given in this trial were:

- **Fevipiprant** was an investigational drug that was being studied for the treatment of nasal polyps.
- **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 were not happening by chance.

Throughout the trial, the participants continued to take a nasal steroid spray for their nasal polyps symptoms.

Participants were also given salbutamol inhalers, or a similar quick relief asthma medicine, 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 16 weeks of treatment with either fevipiprant or placebo, when given along with nasal steroid spray.

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

Did fevipiprant reduce the size of nasal polyps after 16 weeks of treatment compared to placebo?

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

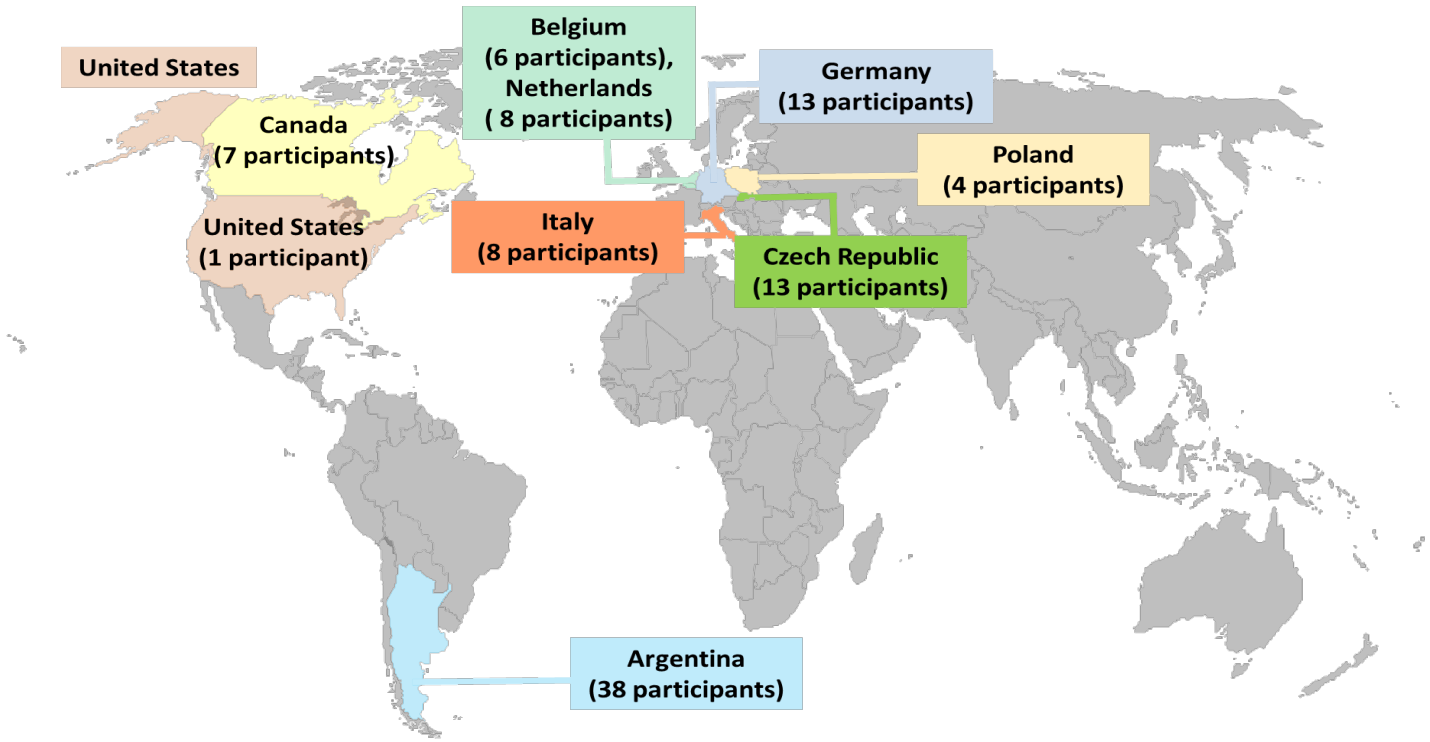
- Did fevipiprant reduce participants’ nasal polyps symptoms after 16 weeks of treatment compared to placebo?

Who was in this trial?

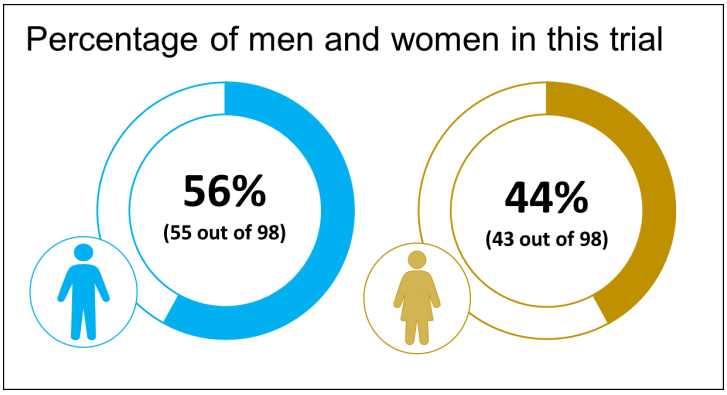
The participants could take part in this trial if they:

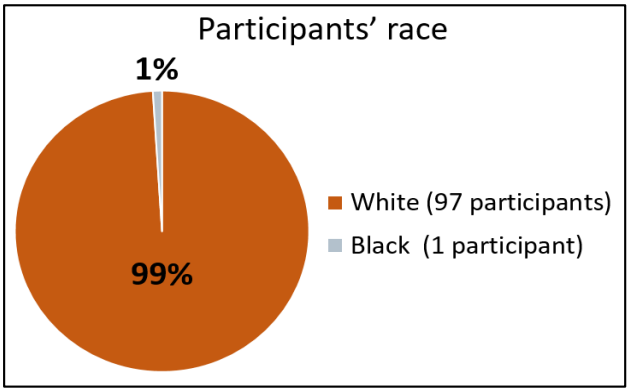
- were 18 years of age or above,
- had nasal polyps and were diagnosed with asthma for at least 6 months,
- did not have any severe episode of worsening of asthma within 6 weeks of starting the trial and
- did not have any heart problems or other serious medical conditions.

A total of 98 participants from 9 countries participated in this trial.



The average age of participants was 50 years. Participants' age ranged from 18 to 80 years. The majority of participants were men, 55 out of 98 (56%).





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 patient 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?

Screening

A total of 168 participants went through a screening period during which the researchers performed certain tests to confirm that they could take part in the trial. However, only 98 participants were included in the trial.

Run-in

During the run-in period, participants were given a nasal steroid spray for their nasal polyps symptoms to take alongside the trial drugs, fevipiprant or placebo. Participants were also provided with rescue medicine, which could be taken when needed to manage episodes of increased asthma. At the end of the run-in period, the researchers confirmed if participants could continue to take part in the trial.

Treatment

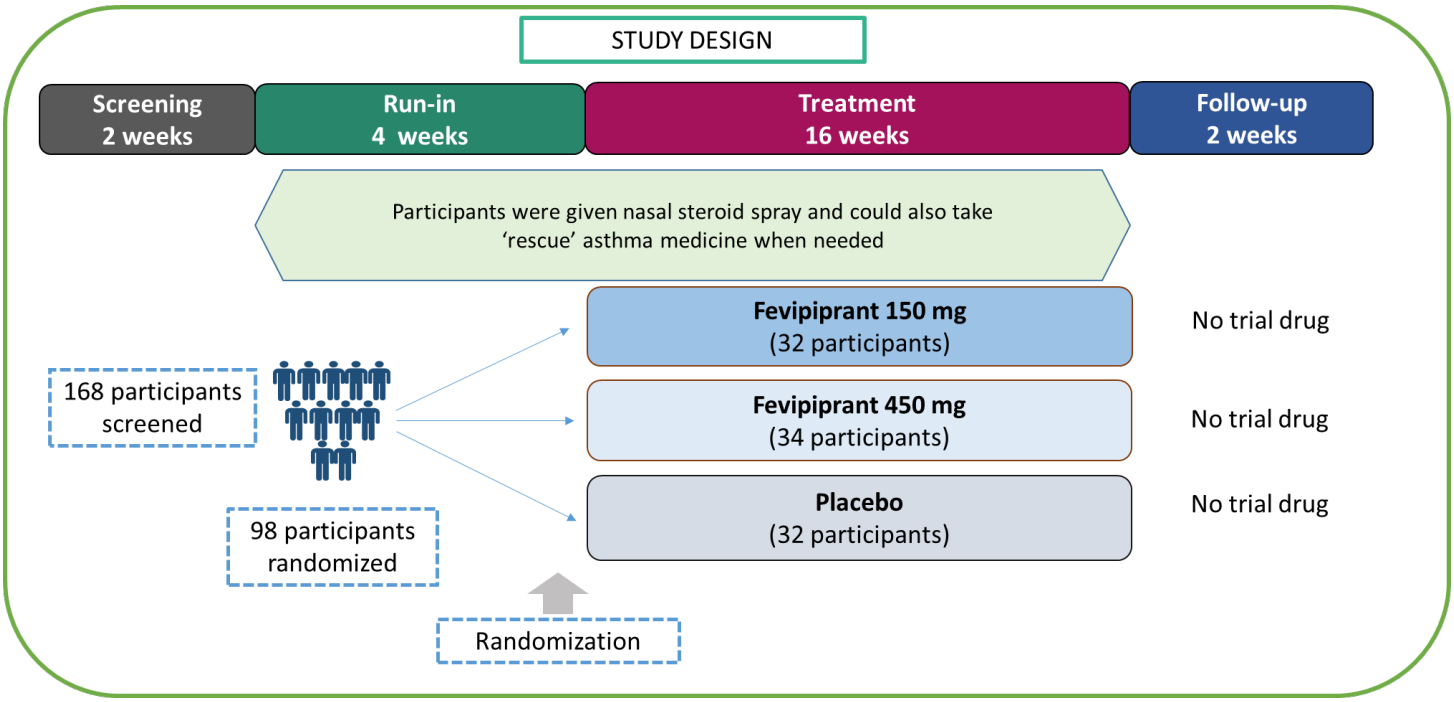
During the treatment period, researchers placed the participants randomly into 1 of 3 groups. This process of randomly dividing participants into different groups is called randomization.

- **Fevipiprant** as 2 tablets once a day, at a dose of 150 milligrams (mg) per day,
- **Fevipiprant** as 2 tablets once a day, at a dose of 450 mg per day,
- **Placebo** as 2 tablets once a day.

As each of the 2 treatment tablets were different in appearance, participants took both types of tablets (one being the fevipiprant tablet and the other placebo, or both placebo) to be sure that they were not aware which treatment they received.

Follow-up

After the treatment period, participants entered into a 2-week follow-up period. During the follow-up period, no trial drug was given to the participants.



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.

Did fevipiprant reduce the size of nasal polyps after 16 weeks of treatment, compared to placebo?

To answer this question, researchers measured the average change in size of participants' nasal polyps after 16 weeks treatment with fevipiprant, compared to placebo.

The results obtained suggested that:

- Overall, there was very little change in the size of participants' nasal polyps from the start of the study to the end of the 16 week treatment period.
- There was little or no difference in how much participants' nasal polyps reduced in size in the fevipiprant treatment groups, compared to placebo.

What were the other results of this trial?

Did fevipiprant improve participants' nasal polyps symptoms after 16 weeks of treatment compared to placebo?

To answer this question, researchers used the following tools to measure any change in participants' nasal polyps symptoms at the start of the trial (Day 1), Week 4, Week 8, Week 12 and the end of the treatment period (Week 16):

Symptoms Questionnaire – participants answered 4 questions on a tablet computer to assess how stuffy their nose was at that time by scoring the symptoms from 0 (not at all) to 3 (severe).

Smell Assessment – for this test there were 40 "scratch and sniff" markers within a kit. Site staff scratched off each in turn and passed it to the participant to try and correctly identify the odor from 4 choices.

The results suggested that after 16 weeks of treatment there was little or no improvement in the nasal polyps symptoms of participants who took fevipiprant compared to placebo.

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?

41 out of 98 participants (42%) had adverse events. There were no serious adverse events, trial drug discontinuations or deaths reported during the trial.

Adverse events were reported in:

- 17 out of 32 participants (53%) in the fevipiprant 150 mg group,
- 13 out of 34 participants (38%) in the fevipiprant 450 mg group,
- 11 out of 32 participants (34%) in the placebo group.

What were the most common non-serious adverse events?

The most common non-serious adverse events that happened in at least 5 out of 100 (5%) participants in any group are presented below.

Number of Participants (%) With Most Common Adverse Events

	Fevipiprant 150 mg (Out of 32 participants)	**Fevipiprant 450 mg** (Out of 34 participants)	**Placebo** (Out of 32 participants)
Cold sores **(Oral herpes)**	1 (3%)	2 (6%)	0
Fever **(Pyrexia)**	2 (6%)	0	0
Flu **(Influenza)**	2 (6%)	1 (3%)	2 (6%)
Headache **(Headache)**	2 (6%)	0	0
Increase in body weight **(Weight increased)**	2 (6%)	0	0
Increase in pancreatic test value of lipase in the blood **(Lipase increased)**	2 (6%)	0	0
Nose and throat infection **(Nasopharyngitis)**	1 (3%)	0	2 (6%)
Stuffy nose **(Nasal congestion)**	2 (6%)	0	0
Swelling in the air filled spaces around the nasal cavity **(Paranasal sinus inflammation)**	0	0	2 (6%)
Swelling of the nasal passages **(Sinusitis)**	3 (9%)	1 (3%)	2 (6%)
Worsening of asthma **(Asthma)**	2 (6%)	3 (9%)	1 (3%)

How was this trial useful?

This trial helped researchers learn about the effects of fevipiprant on nasal polyps in people who also had asthma. Results from this trial may be used in other clinical trials for people with nasal polyps and asthma.

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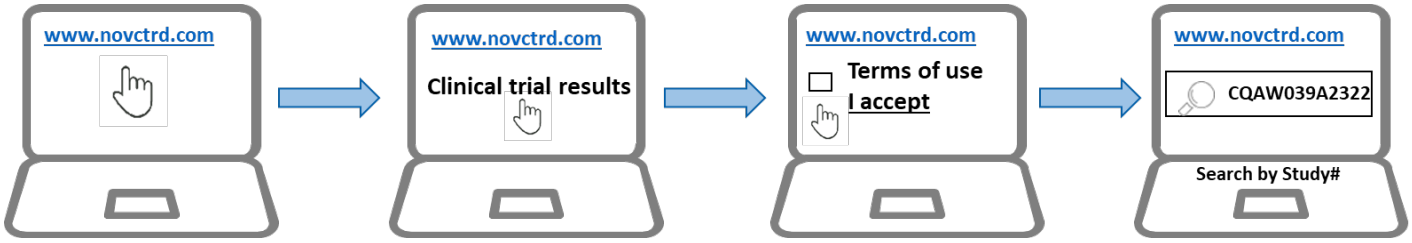
Where can I learn more about this trial?

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 NCT03681093 in the search field.
- https://www.clinicaltrialsregister.eu/ctr-search/search Use the EudraCT identifier 2018-002073-22 in the search field.

Full clinical trial title: A multicenter, randomized, double-blind, parallel-group, placebo-controlled study of fevipiprant once daily plus standard-of-care (SoC) for assessment of the efficacy in reduction of nasal polyps size in patients with nasal polyps and concomitant 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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www.novartisclinicaltrials.com