NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the safety and blood levels of fevipiprant in children with asthma

Protocol number: CQAW039B2201

Thank You!

Novartis, the sponsor of this clinical trial, would like to thank all the children and their parents for taking part in this trial for the drug QAW039, also known as fevipiprant. You helped researchers learn more about the safety and blood levels of fevipiprant in children with asthma.

This summary only shows the results of a single clinical trial. If you and your child 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 started in May 2019 and ended in January 2020. Each child could take part in this trial for 8 days.

The children's trial ended early because fevipiprant (pronounced fe-VI-pi-prant) failed to show benefit in adults with asthma in other clinical trials. The researchers collected information on the trial treatment (fevipiprant) 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. Asthma is a disease that squeezes the air tubes narrow and tight. This makes breathing hard. It can cause symptoms like coughing, wheezing, and tightness in the chest. Asthma in children can:

- make them cough, wheeze and gasp for air,
- stop them from playing sports and going to school,
- make them feel miserable,
- need them to be in a hospital sometimes.

In this trial, children were already taking other medicines for asthma. Some children with asthma need to take more than one medicine. Therefore, researchers wanted to measure the blood levels and safety of fevipiprant in children when given along with other asthma medicines.

Trial drug

Fevipiprant (QAW039): A drug which is given as a chewable tablet and was being tested in adults to see if it helps to treat asthma. A chewable tablet might be preferred for children because it is easier to take than an inhaler.

Children could continue taking their regular asthma medicines in addition to fevipiprant. Children could also take an additional medicine to treat any sudden worsening of their asthma symptoms if it was needed. This medicine was known as "rescue" medicine.

Trial purpose

This trial was done to learn more about fevipiprant. The main question the researchers wanted to answer in this trial was:

What happened to fevipiprant when it was in the blood of children?

To answer the above question researchers measured:

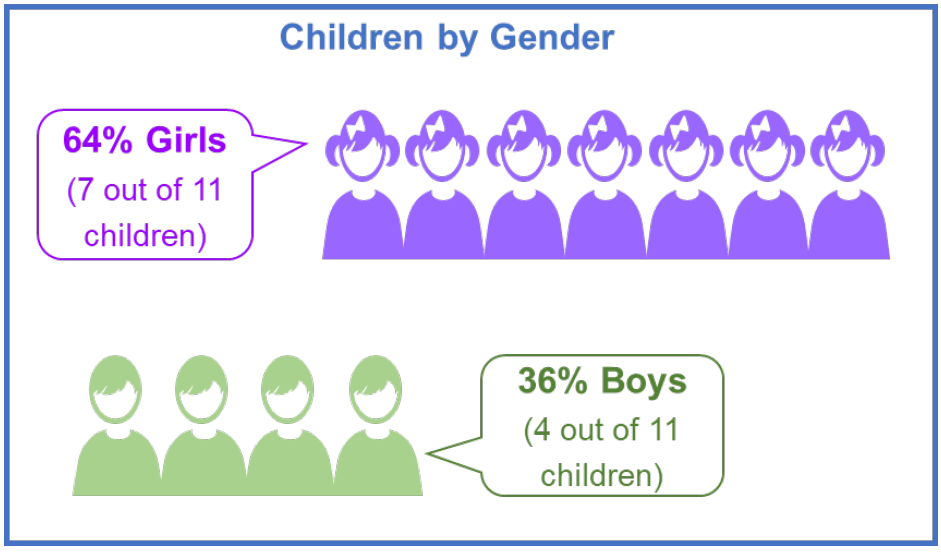
- the total level of fevipiprant in the children's blood,
- the highest level of fevipiprant in the children's blood,
- the time taken to reach the highest level of fevipiprant in the children's blood,
- how quickly fevipiprant was removed from the blood once a consistent level was reached.

Who was in this trial?

The children could take part in this trial if they:

- were between 6 and 11 years of age,
- had asthma for 6 months or more before the trial started,
- did not have an allergy to fevipiprant or a similar treatment in the past,
- were able to eat banana and/or yogurt,
- did not have lung disease other than asthma in the past.

A total of 11 children from the United States took part in this trial. The average age of the children was 9 years.



What kind of trial was this?

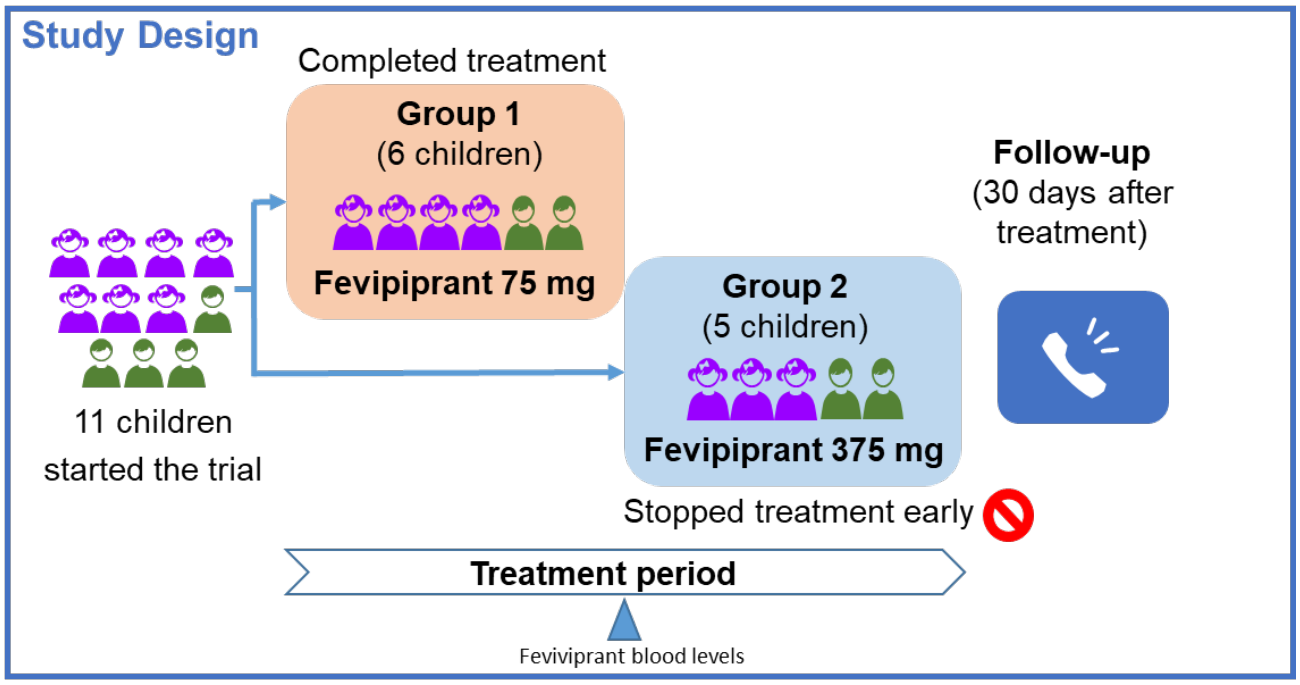
This was an open-label trial, which means that the researchers, the children and their parents knew what treatment (fevipiprant) was given to the children.

What happened during this trial?

At the start of the trial, researchers checked the children's asthma and overall health to make sure they could be in this trial. Researchers divided the children into 2 groups:

- **Group 1:** Children were given fevipiprant as a chewable tablet, at a dose of 75 milligrams (mg) per day,
- **Group 2:** Children were given fevipiprant as a chewable tablet, at a dose of 375 mg per day, based on the blood levels of fevipiprant in Group 1. Children in Group 2 did not start taking fevipiprant until all the children in Group 1 completed treatment.

The children took fevipiprant once a day for 8 days. This trial was stopped early and children in Group 2 could not complete the treatment. Therefore, only the results of Group 1 are included in this summary.



Researchers checked the children's health throughout the trial. Children continued to take their regular asthma medicine throughout the trial. During the follow-up period, the children were not given fevipiprant. At the follow-up visit, information on the children's health was collected over a telephone call.

Why did researchers measure fevipiprant in the children's blood?

Blood was taken to find out

- The **total amount** (level) of fevipiprant.

  This showed researchers how much fevipiprant is available in the blood over time.

- The **highest level** of fevipiprant.

  This helped researchers to understand how quickly fevipiprant is taken up in the body.

- How **much time** it took to reach the **highest level** of fevipiprant?

  This also helped researchers understand how quickly fevipiprant is taken up in the body.

- How **quickly** the children's body systems lowered the amount of fevipiprant to a **steady level**?

  Together with the information on blood levels, this helped researchers decide how much and how often to give fevipiprant.

What were the key results of this trial?

This is a summary of the average results for all children in treatment Group 1. It does not show the results of each individual child. Results of individual children could be different from the results of the total group of children. A detailed presentation of the results can be found on the websites listed at the end of this summary.

What happened to fevipiprant when it was in the blood of children?

Researchers found that 75 mg of fevipiprant was taken up very quickly within the body. The highest level in the blood was reached 1 hour after taking fevipiprant by mouth.

Researchers chose a daily dose of 375 mg for Group 2, based on the blood test results of Group 1.

The trial was stopped early before children completed Group 2 because fevipiprant failed to show benefit in adults with asthma in other clinical trials.

What medical problems did the children have during the trial?

Medical problems that happen in clinical trials are called “adverse events”.

There were **no medical problems or adverse events** reported by children who took fevipiprant chewable tablet.

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

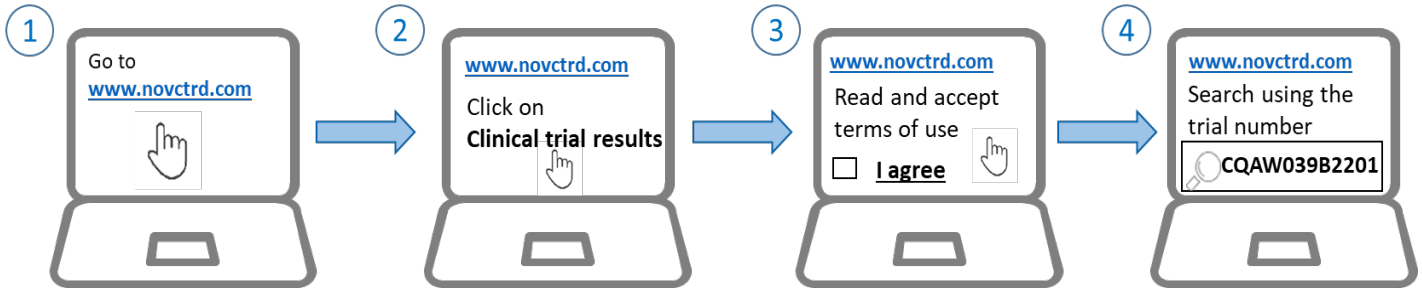
How was this trial useful?

This trial helped researchers find out if fevipiprant was safe to use and to understand blood levels of fevipiprant in children aged 6 to 11 years with asthma. The researchers ended this trial early because fevipiprant failed to show benefit in adults with asthma in other clinical trials.

If you and your child 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 also find more information about this trial on the following websites:

- www.clinicaltrials.gov Use the NCT identifier NCT03650400 in the search field.
- https://www.clinicaltrialsregister.eu/ctr-search/search Use the EudraCT identifier 2018-003920-35 in the search field.

Full clinical trial title: A multicenter, open-label, 8 day treatment study to assess the pharmacokinetics, safety and tolerability of fevipiprant delivered via a once daily chewable tablet in children aged 6 to <12 years 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.

NOVARTIS

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

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