



Dear Parents and Caregivers,

Novartis, the sponsor of this clinical trial *CQAW039B2201: A clinical trial to learn about the safety and blood levels of fevipirant in children with asthma*, would like to thank all the children and their parents for taking part in this trial for the drug QAW039, also known as fevipirant.

You and your child gave up your precious time to be part of our trial. Your child blew into machines, chewed tablets and gave samples of their blood to help researchers learn more about the safety and blood levels of fevipirant in children with asthma.

Here is a summary of what happened in the trial. We have provided 3 versions. A version for adults, and 2 versions for children, all of which can also be found at [www.novartisclinicaltrials.com](http://www.novartisclinicaltrials.com). Please read the adult version first, for your awareness. Based on your child's reading level, select 1 of the 2 children's versions to read with your child. *Please contact the research doctor if you have any questions.*

Sincerely,

The Novartis Clinical Trial Team

Please see below the Thank you note  
for children 6-8 years of age





# Thank you

for taking part in this clinical trial!

You helped us test a trial drug called

**Fe Vi Pi Prant**

OR

**Fe Vi**

We learned what happens to **fevi** inside the body of children with asthma.

We hope you feel proud of your role as a clinical trial participant.



Please ask your parents and trial doctor if you have any questions about the trial.

Please see below the Plain Language Trial Summary  
for Children 9-11 years of age





**Thank you**  
**for taking part**  
**in this clinical trial!**

Because of your help, we learned  
more about a trial drug called

**Fe Vi Pi Prant**

OR

**Fe Vi**

for children with asthma.  
We hope you feel proud of your role  
as a clinical trial participant.

This summary only shows the results of a single clinical trial (CQAW039B2201).  
Please ask your parents and trial doctor if you have any questions about the trial.

# What is a clinical trial and why was one needed?

A clinical trial is a careful research study to find out the answer to important questions during research. People who do research are called researchers. Researchers want to find better medicines for children who have asthma.

This summary tells you about this trial, and what we found out.



## What was the trial drug?

**Fevi** is a drug which is given as a chewable tablet and is being tested for the treatment of asthma in children. It helps to open the airways in the lungs, making it easier to breath.

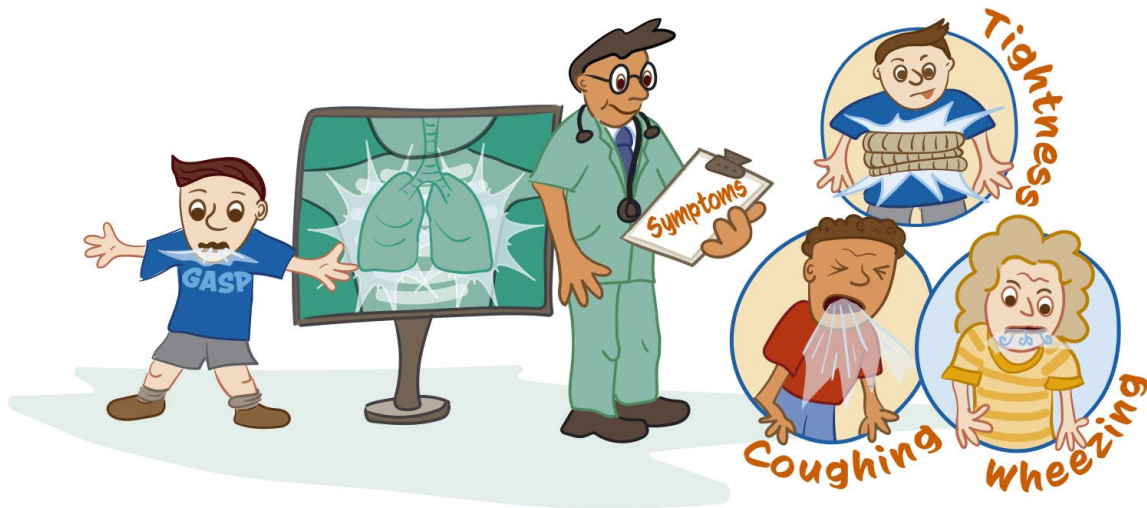


During the trial, children could continue taking their regular asthma medicines in addition to **Fevi**.

Researchers wanted to measure the blood levels and safety of **Fevi** in the children when given along with other medicines.

# What is asthma?

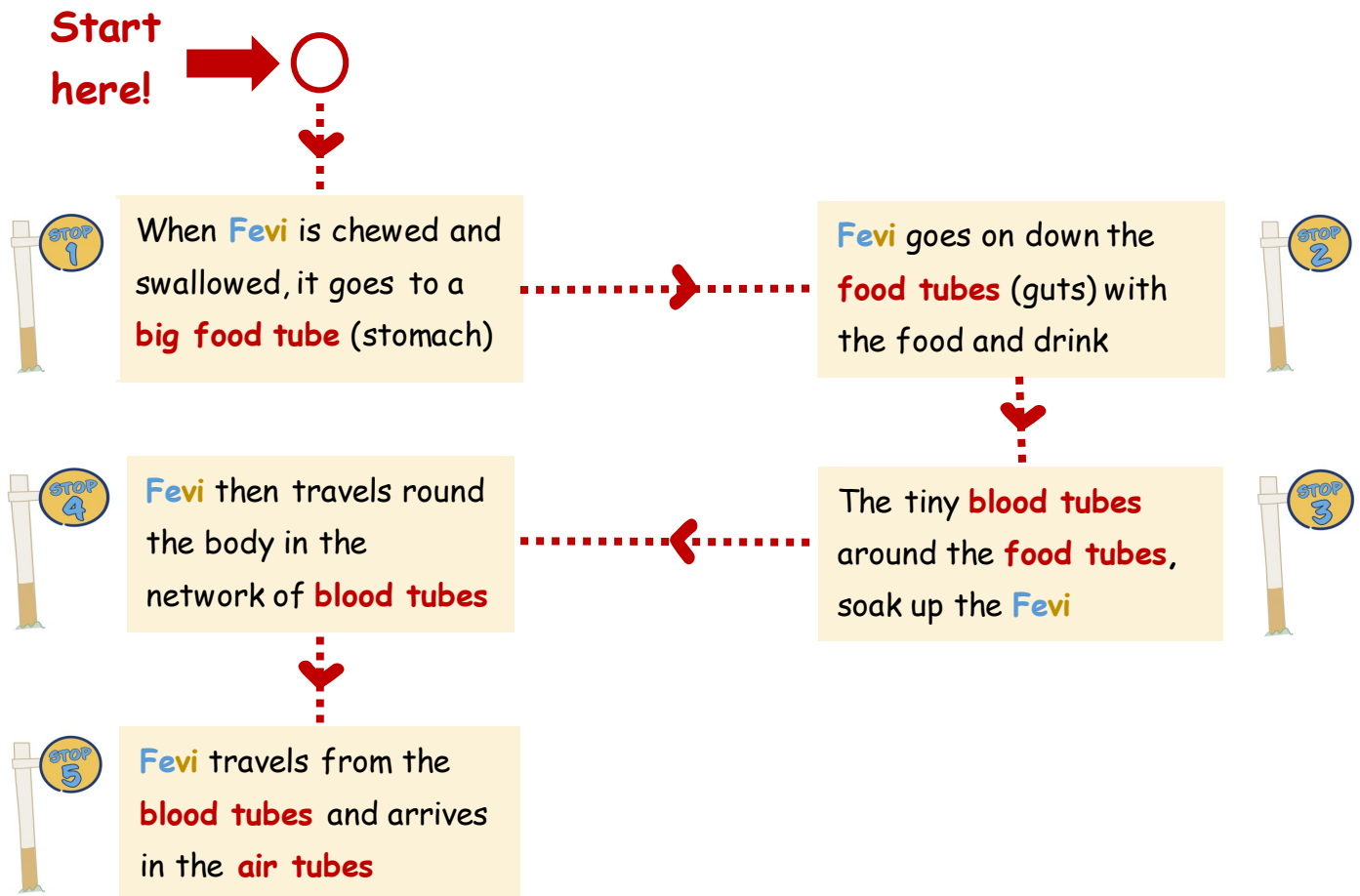
As you breathe, air goes in and out of air tubes in your chest. Asthma is a disease that squeezes the air tubes narrow and tight. This makes breathing hard.



Asthma can

- Make you cough, wheeze and gasp for air.
- Stop you from playing sports and going to school.
- Make you feel miserable.
- Need you to be in a hospital sometimes.

# How does Fevi get to someone's air tubes?



So, the researchers wanted to find out

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

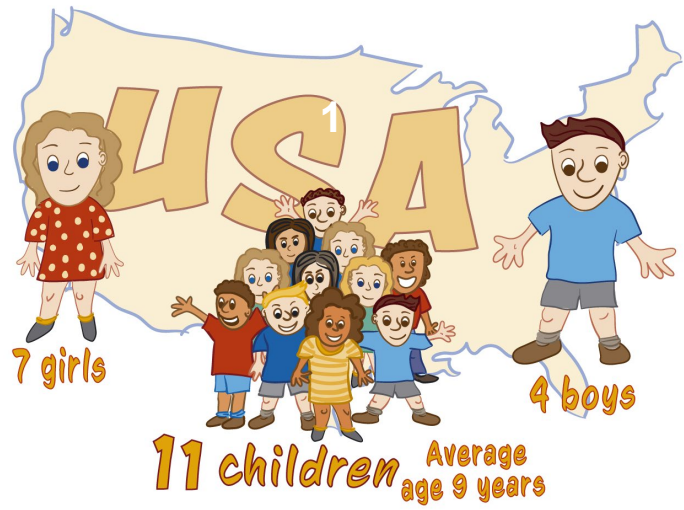




# Who was in this trial?

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



# How long was this trial?



This trial started in May 2019 and ended in January 2020. An individual child could take part for 8 days.

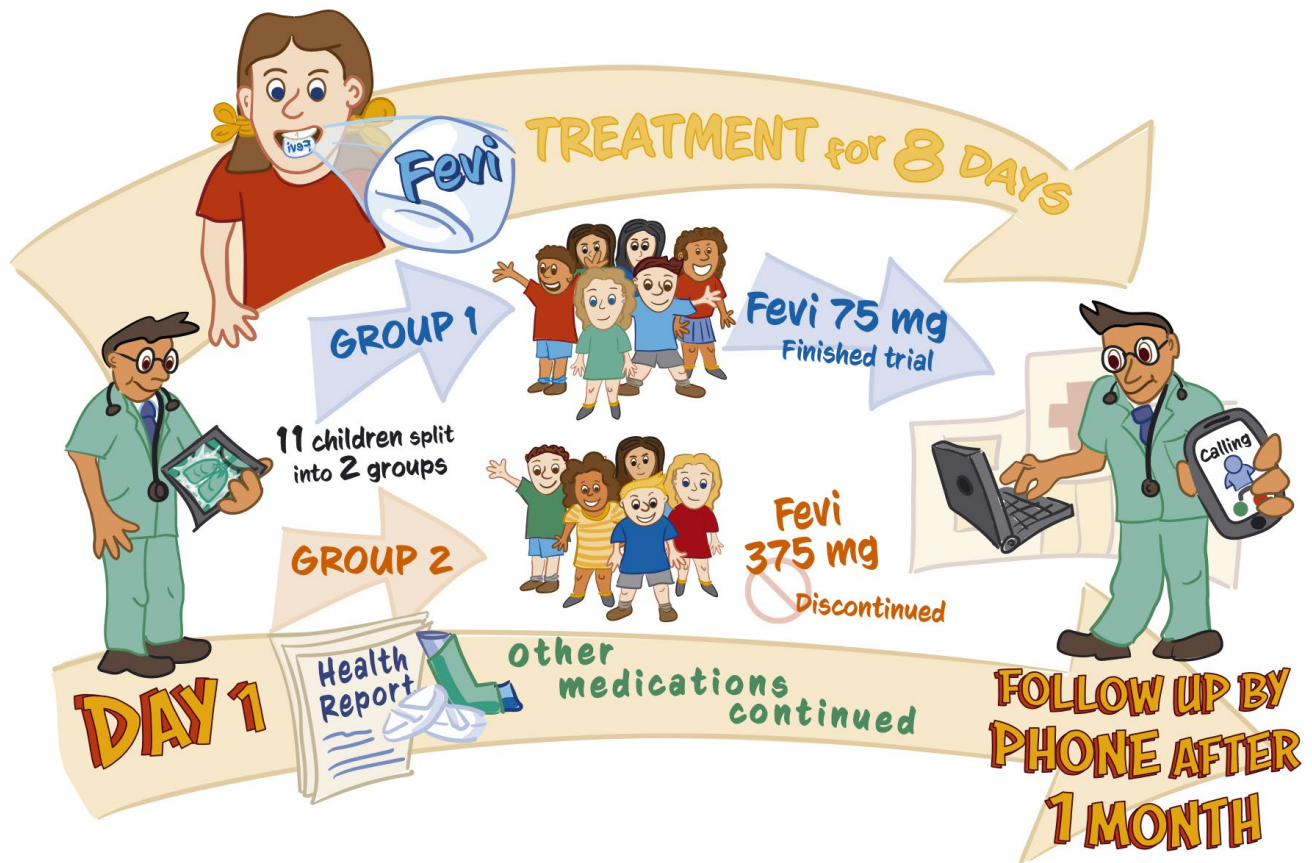
The trial was ended early because **Fevi** failed to show benefit in adults with asthma in other clinical trials.

# What happened during this trial?

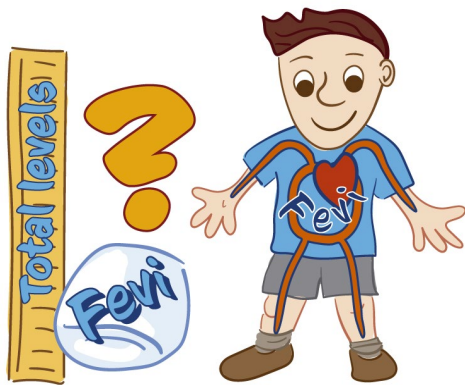
Researchers divided the children into 2 groups, **Group 1** and **Group 2**.

The children took **Fevi** once a day for 8 days. Researchers also checked the children's health throughout the trial.

This trial was stopped early and children in **Group 2** could not complete the treatment. Therefore, only the results of **Group 1** are included.



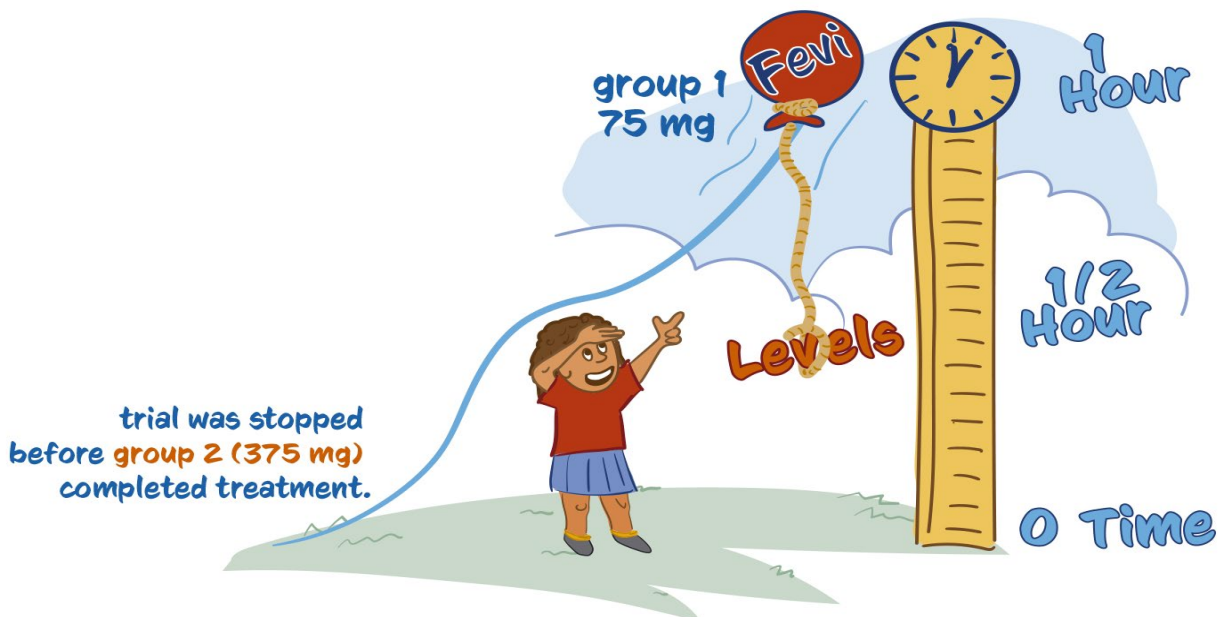
# What was learned in this trial?



Here is a summary of what we learned from the results of all the children in treatment **Group 1**.

1 **75 mg** of **Fevi** was taken up and distributed very quickly within the body.

2 The highest level in the blood was reached **1 hour** after taking **Fevi** by mouth.



Making these measurements helped researchers to decide how much **Fevi** should be given to children, and how often.

3 Based on the results of **Group 1**, a dose of **375 mg** per day was chosen for **Group 2**.

## Did the children have any medical problems during the trial?

No, none of the children had any medical problems during the trial.



## Was this trial useful?

Yes, it was. You helped the researchers understand more about what happens to **Fevi** in the children's blood.

If you have any questions about these trial results, please talk to your parents and trial doctor.

## Thank you!

Thanks again for taking part in this trial. You helped researchers answer important health questions and test a new medical treatment.



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

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

[www.novartisclinicaltrials.com](http://www.novartisclinicaltrials.com)