ForPatients
by Roche

Influenza

A clinical trial to look at changes in flu virus before and after treatment with baloxavir marboxil in children – to understand more about treatment resistance

A Surveillance Study of Susceptibility to Baloxavir Marboxil in Participants With Influenza

Trial Status	Trial Runs In	Trial Identifier
Recruiting	4 Countries	NCT06094010 2023-504672-22-00 CV44536

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

The purpose of this study is to evaluate the pre-treatment and single-dose post treatment susceptibility of baloxavir marboxil in participants aged 1 to <12 years with influenza.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT06094010 2023-504672-22-00 CV44536
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=1 Year & <= 11 Years	No

1. Why is the Pebblestone clinical trial needed?

Influenza (the flu) is caused by a virus that can quickly spread between people and cause symptoms such as sore throat, cough, fever, headache and muscle pains. The flu can also cause more serious symptoms, for example, in young or older people. People can be vaccinated against the flu to prevent it from spreading, but the number of people who have a flu vaccine each year varies, and vaccines do not work as well in very young or older people or from one flu season to another. This is because the flu virus can sometimes change (known as ‘virus mutation’) over time.

Treatments that can stop the flu virus from making copies of itself, such as baloxavir marboxil, are approved in many countries for adults and children. But treatments can stop working well (also known as ‘resistance’) if the flu virus changes in certain ways. When children have the flu, they can make a higher number of flu viruses than adults and for a longer period of time. This means that the flu virus has more of a chance to change. Researchers have discovered a few ways that flu viruses can change with other treatments but have yet to fully look at how the flu virus changes in children who are treated with baloxavir marboxil. This clinical trial aims to look at changes in the flu virus before and after treatment with baloxavir marboxil in children. Researchers will also look at the resistance of flu virus to treatment with baloxavir marboxil.

2. How does the Pebblestone clinical trial work?

This clinical trial is recruiting children with the flu. Children can take part if they and their caregiver agree for the child to have nose swabs taken (by brushing the inside of the nose with a cotton bud) throughout the trial and if the child tests positive for the flu but not for COVID-19.

Children who take part in this clinical trial (participants) will have nose swabs taken before being given a single dose of the clinical trial treatment baloxavir marboxil on Day 1. The child’s caregiver or the clinical trial doctor will take swabs on Day 4, and the clinical trial doctor will take swabs on Days 6 and 10. These trial visits will include checks to see if the child has or has had any side effects. About 1 month after being given treatment, the clinical trial team will contact the caregiver by telephone to see how the child is feeling. The total time of participation in the clinical trial will be about 1 month. Participants can leave the clinical trial at any time.

3. What are the main endpoints of the Pebblestone clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the flu virus has changed) is the number of participants with the flu virus that has certain changes at Day 1 (before treatment) and 4, 6 and 10 days after treatment.

The other clinical trial endpoints include the number of participants:

- Aged under 5 years versus aged over 5 years old with the flu virus that has certain changes before and after treatment
- With flu virus changes after treatment in ways not recorded by any researchers previously
- Who had been vaccinated versus who had not been vaccinated against the flu virus (within 6 months before the start of the trial) and who have flu virus after treatment that has certain changes
- With different types of flu virus

Researchers will also measure the amount of flu virus in nose swabs before and after treatment, how much flu viruses become resistant to baloxavir marboxil after treatment and the number and seriousness of any side effects.

4. Who can take part in this clinical trial?

Children can take part in this trial if they are between 1–11 years old, have symptoms of the flu at the beginning of the trial and test positive for the flu virus and negative for the COVID-19 virus. Children may not be able to take part in this trial if their flu symptoms started more than 2 days before the start of the trial, they have serious flu symptoms and need to be treated in a hospital, they have certain medical conditions such as cancer, other infections that require treatment, or they have been given certain treatments shortly before the start of the trial, including baloxavir marboxil or drugs that affect the immune system (such as steroids).

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be given a single dose of baloxavir marboxil as a liquid (to be swallowed). This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.

6. Are there any risks or benefits in taking part in this clinical trial?

Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly. Participants will be told about the known side effects of **baloxavir marboxil** and possible side effects based on human and laboratory studies or knowledge of similar drugs. **Baloxavir marboxil** will be given as a liquid (to be swallowed). Participants will be told about any known side effects of swallowing liquids.

Potential benefits associated with the clinical trial

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Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with a similar medical condition in the future.