ForPatients
by Roche

Influenza

A clinical trial to look at how well baloxavir reduces the spread of the flu within households, compared with a placebo (no active treatment).

Study to Assess the Efficacy of Baloxavir Marboxil Versus Placebo to Reduce Onward Transmission of Influenza A or B in Households

Trial Status	Trial Runs In	Trial Identifier
Completed	18 Countries	NCT03969212 2018-004056-37 MV40618

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

Trial Summary:

Otherwise healthy index patients (IP) are randomized to either baloxavir marboxil or placebo if their influenza symptoms onset was within 48 hours of screening. Their households are enrolled within 24 hours of randomization if at least 1 household contacts (HHC) have not received influenza vaccine within 6 months of screening and if all HHC screen negative for influenza infection. The main endpoints are assessed based on multiple respiratory swabs, obtained from both IP and HHC up to 9 (+/-1) days post IP randomization, and through the assessment of symptoms.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03969212 2018-004056-37 MV40618
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=5 Years & <= 64 Years	No

How does the CENTERSTONE clinical trial work?

This clinical trial is recruiting people who have a disease called influenza, which is more commonly known as the flu. In order to take part, you must be living with at least one person who has **not** had the flu vaccine within the last 6 months and who shows no signs of having the flu. All of the people that you live with should also be willing to have swabs taken from their noses.

The purpose of this clinical trial is to test how well a drug called baloxavir can reduce the spread of flu within your home, compared with a placebo. If you have flu and would like to take part in this clinical trial, you will receive either baloxavir or a placebo. Your household contacts will not be treated, but will require swabs to test for flu at various points in the trial.

How do I take part in this clinical trial?

Index patients (person with the flu)
To be able to take part in this clincal trial, you must:

- Be aged 5#64 years old
- Have been diagnosed with the flu and your symptoms must have started within the last 2 days

You must not:

- Have been diagnosed with or given treatment for the flu in the last 30 days or diagnosed with COVID-19 in the last 30 days
- Have a health condition or disease that puts you at higher risk of getting sick from the flu e.g. have heart disease, be pregnant or immunocompromised (have a weakened immune system) *(for more information visit https://www.cdc.gov/flu/highrisk/index.htm)*

Household contacts (the people that you live with)
All of the people that you live with must be willing to have swabs taken from their noses and households must contain at least one person who has **not** had the flu vaccine. In addition, households must **not** have:

- Anyone who has been diagnosed with the flu or COVID-19 in the last 4 weeks
- Anyone aged 2 years old or under
- Anyone who is immunocompromised

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

All index patients (people with the flu) who join this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Baloxavir, given as a tablet to swallow once (children under the age of 12 will be given baloxavir as a liquid)
- OR placebo, given as a tablet to swallow once (children under the age of 12 will be given placebo as a liquid)

You will have an equal chance of being placed in any group.

Household contacts will not receive any treatment.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a ‘placebo’). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

How often will I be seen in follow-up appointments, and for how long?

Index patients will be given the clinical trial treatment (baloxavir or placebo) only once.

Within 1 day of being given treatment, either a nurse will visit your home (or the people you live with will be asked to come to the clinical trial site) to check that the people you live with meet the requirements for the trial and to take swabs from their noses to check for the flu virus and to check they do not have COVID-19.

During the clinical trial, the nurse will then visit your home or you will visit the clinical trial site every couple of days to check how you are responding to the treatment and to monitor

any side effects that you may be having. The nurse or clinical trial staff will also complete necessary checks and take swabs to check for flu virus from the people you live with who have agreed to participate in the clinical trial, as follows:

- Day 3 after treatment: Index patient swab
- Day 5 after treatment: Index patient and household contacts swab. The nurse will also assess household contacts for flu symptoms
- Day 9 after treatment (end of study): Index patient and household contacts swab. The nurse will also assess household contacts for flu symptoms
- These visits will stop on Day 9 after being given clinical trial treatment
- Clinical trial staff will also telephone on Day 21 to follow up on anyone under the age of 12

If a household contact develops flu symptoms between these visits, they will be asked to have an unscheduled visit to take a swab. Either a nurse will visit your home or the household contact with flu symptoms will be asked to come to the clinical trial site.

Your swabs will be tested to confirm if the amount of flu virus in your body is going down. The swabs taken from your household contacts will be tested to see if any of them have caught the flu virus, as well as COVID-19.

Any or all home visit assessments can take place at the clinical trial site if you or the people you live with prefer this. If any person in the household (index patient or household contact) tests positive for SARS-CoV-2 (the virus that causes COVID-19), then all people in the household will not continue with the trial. You and the people you live with are free to leave this clinical trial at any time.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT03969212

Trial-identifier: NCT03969212