ForPatients
by Roche

Acute Ischemic Stroke

A clinical trial to compare balovaptan with placebo in people who have had a large stroke within the last 12 hours and are at high risk of developing severe brain swelling

Study to Evaluate The Safety and Efficacy of Balovaptan in Participants With Acute Ischemic Stroke at High Risk of Developing Malignant Brain Edema

Trial Status	Trial Runs In	Trial Identifier
Withdrawn	1 Countries	NCT05399550 WC42759

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

Trial Summary:

This study is designed to evaluate the safety, efficacy, and pharmacokinetics of balovaptan compared with placebo in participants with acute ischemic stroke (AIS) at risk of developing Malignant Cerebral Edema (MCE)

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT05399550 WC42759
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 80 Years	No

How does the EBBTIDE (WC42759) clinical trial work?

This clinical trial is recruiting people who have had a stroke as a result of the brain's blood supply being cut off by a blockage (large vessel occlusion [LVO]). In order to take part, the infusion of the clinical trial drug must be started within 12 hours from the start of the stroke symptoms, and you must be at high risk of developing severe brain swelling (malignant cerebral oedema).

The purpose of this clinical trial is to see whether balovaptan helps to decrease the amount of brain swelling in patients with severe stroke. If you take part in this clinical trial,

you will receive either balovaptan or placebo (a medicine with no active ingredients), in addition to your normal medical care.

Please note, this document is intended for the patient (referred to here as “you”) or their legally authorised representative. If you can take part in this clinical trial, you or your legally authorised representative will need to sign an informed consent form, which provides all the information you need to make the decision about taking part in the clinical trial.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have been diagnosed with an LVO and be at high risk of developing severe brain swelling, and be able to receive the clinical trial treatment within 12 hours of your stroke symptoms starting. If you woke up with stroke symptoms that were not present before you fell asleep (a wake-up stroke), you must be able to receive the clinical trial treatment within 8 hours of waking up.

You may not be able to take part in this clinical trial if you take certain other medications or have certain medical conditions. If you are pregnant or breastfeeding, or intending to become pregnant shortly after the clinical trial, you will not be able to take part.

If your doctor thinks that you might be able to take part in this clinical trial, they may refer you to the closest clinical trial doctor. They will give you and your legally authorised representative all the information needed to make the 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 already had some of the tests, they may not need to be done again.

Before starting the clinical trial, you and your legally authorised representative will be told about any risks and potential 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?

Everyone who joins this clinical trial will be split into one of two groups randomly (like flipping a coin) and given either:

- Balovaptan, as an infusion into the vein in three doses. The first dose must be given within 12 hours of your stroke symptoms starting. The second dose will be given roughly 1 day after the first dose, and the third dose will be given roughly 1 day after that
- OR placebo, as an infusion into the vein in three doses on the same schedule

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

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 see if the clinical trial treatment being investigated actually shows an effect, and that the doctor or the patients do not accidentally influence the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, if there are any safety concerns, your clinical trial doctor can find out which group you are in.

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

You will be given balovaptan or placebo over the course of 3 days. You are free to stop this treatment at any time. To look for any brain swelling, you will have a brain scan at screening, every day for the first 3 days and another scan roughly 4–5 days after your stroke symptoms started. You will be seen regularly by a member of the clinical trial team while you are in hospital, followed by two further visits roughly 30 days (1 month) and 90 days (3 months) after your first dose of clinical trial medication. This is in addition to your regular medical care. These follow-up visits will include checks to see how you are functioning with everyday activities, such as bathing or walking, and any side effects that you may be having.

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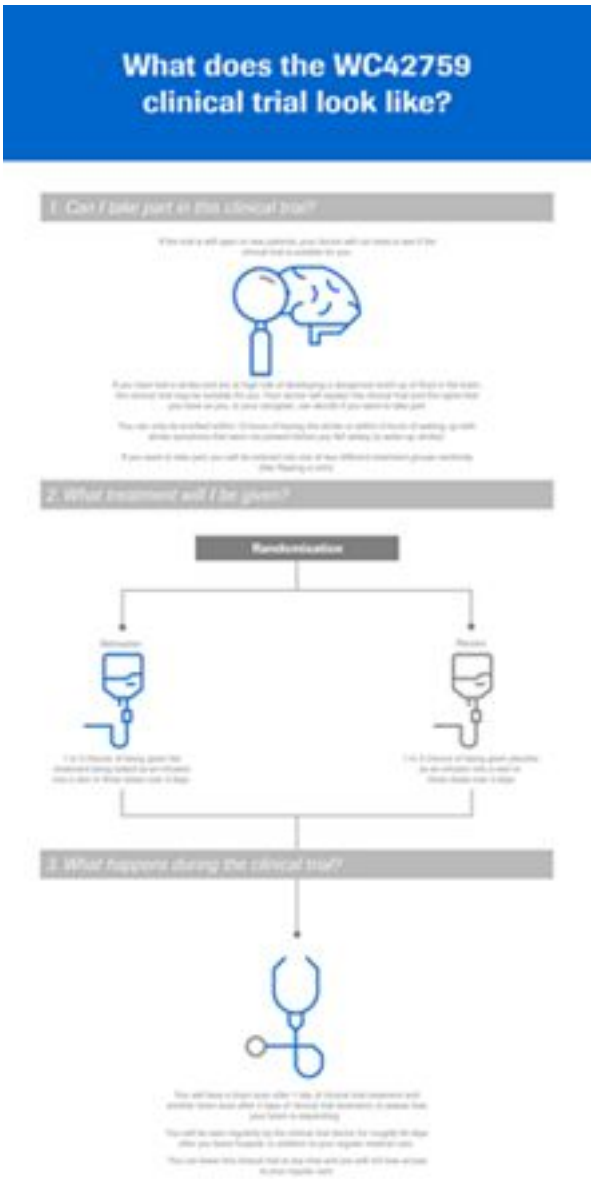

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What happens if I am unable to take part in this clinical trial?

If this clinical trial is not right for you, you will not be able to take part. Your doctor may 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 ForPatients page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05399550

Trial-identifier: NCT05399550