ForPatients
by Roche

Metastatic Breast Cancer Breast Cancer HER2-Positive Breast Cancer

A clinical trial to compare trastuzumab emtansine plus atezolizumab with trastuzumab emtansine alone in patients with a particular type of breast cancer that has spread to other parts of the body and who already received trastuzumab- (with or without pertuzumab) and taxane-based therapy.

A Study of Trastuzumab Emtansine in Combination with Atezolizumab or Placebo As a Treatment for Participants with Human Epidermal Growth Factor 2 (HER2)-Positive and Programmed Death-ligand 1 (PD-L1)-Positive Locally Advanced (LABC) or Metastatic Breast Cancer (MBC)

Trial Status	Trial Runs In	Trial Identifier
Terminated	21 Countries	NCT04740918 2020-002818-41 MO42319

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 will evaluate the efficacy, safety and patient-reported outcomes of trastuzumab emtansine plus atezolizumab compared with trastuzumab emtansine plus placebo in participants with HER2-positive and PD-L1-positive LABC or MBC.Participants must have progressed either during or after prior trastuzumab- (+/- pertuzumab) and taxane-based therapy for LABC/MBC; or during (or within 6 months after completing) trastuzumab- (+/- pertuzumab) and taxane-based therapy in the neoadjuvant and/or adjuvant setting.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT04740918 2020-002818-41 MO42319
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the KATE3 clinical trial work?

This clinical trial is recruiting people who have a particular type of breast cancer (HER2-positive and PD-L1-positive breast cancer) that has spread to other parts of the body (locally advanced or metastatic breast cancer). In order to take part, patients must have already been treated with trastuzumab- (with or without pertuzumab) and taxane-based therapy for their breast cancer.

The purpose of this clinical trial is to compare the effects, good or bad, of trastuzumab emtansine plus atezolizumab versus trastuzumab emtansine alone in this group of breast cancer patients. In this clinical trial, you will get either trastuzumab emtansine plus atezolizumab or trastuzumab emtansine plus placebo.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must be at least 18 years old and diagnosed with locally advanced or metastatic breast cancer. Your cancer must be positive for particular proteins called HER2 and PD-L1, and you must have previously received treatment with trastuzumab- (with or without pertuzumab) and taxane-based therapy for your breast cancer.

You must not have previously received trastuzumab emtansine for metastatic breast cancer, or have cancer that has spread to the brain and shows particular symptoms that requires treatment. If you have uncontrolled pain related to your cancer you may not be able to join the trial unless you are on a stable regimen of pain medication.

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, both men and 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 2 groups randomly (like flipping a coin) and given either:

- Trastuzumab emtansine plus atezolizumab, both given as an infusion into the vein every 3 weeks
- OR trastuzumab emtansine plus placebo, both given as an infusion into the vein every 3 weeks

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’) instead of atezolizumab. A placebo is used to show that neither the doctor nor the patients 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? You will be given the clinical trial treatment trastuzumab emtansine plus atezolizumab OR trastuzumab emtansine plus placebo for as long as it can help you. You are free to stop this treatment at any time. After being given treatment, you will be seen regularly by the clinical trial doctor. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After being given your last dose, you will be seen by the clinical trial doctor between 28 and 42 days later, and then contacted by phone or clinic visits once every three months after that.

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

Trial-identifier: NCT04740918