ForPatients
by Roche

Breast Cancer HER2-Positive Breast Cancer

A Clinical Trial of Atezolizumab plus Chemotherapy, Trastuzumab and Pertuzumab for Patients with HER2-Positive Breast Cancer (IMpassion050)

A Study To Evaluate the Efficacy and Safety Of Atezolizumab or Placebo in Combination With Neoadjuvant Doxorubicin + Cyclophosphamide Followed By Paclitaxel + Trastuzumab + Pertuzumab In Early Her2-Positive Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	12 Countries	NCT03726879 BO40747

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 (also known as IMpassion050) will evaluate the efficacy and safety of atezolizumab compared with placebo when given in combination with neoadjuvant dose-dense anthracycline (doxorubicin) + cyclophosphamide followed by paclitaxel + trastuzumab + pertuzumab (ddAC-PacHP) in patients with early HER2-positive breast cancer (T2-4, N1-3, M0).

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

NCT03726879 BO40747
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the IMpassion050 clinical trial work? This clinical trial is recruiting people who have a specific type of newly diagnosed breast cancer, called HER2-positive breast cancer, which means that the breast cancer cells have tested positive for the protein HER2.

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 have been diagnosed with HER2-positive breast cancer. You must not have received any previous treatment for your breast cancer.

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 who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of 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 and 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 and 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? This is a ‘placebo-controlled’ clinical trial, which means that while all patients will receive chemotherapy and a treatment that targets HER2, half of all patients will receive a placebo instead of the investigational drug, atezolizumab. A placebo does not contain any active drug. You will not know which treatment you are being given.

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin). After you have been assigned to a group, you will stay in that group for the whole study.

You will firstly receive four rounds of treatment, called ‘cycles’. You will then receive a further four rounds, or cycles, of a different treatment, before having surgery for your breast cancer. After your surgery, you will receive a further 14 rounds of treatment. You will receive different treatment depending on which group you are in:

- Group 1:
    - Cycle 1 – Cycle 4: You will be given atezolizumab and chemotherapy into your vein (this is called an ‘intravenous infusion’) once every 2 weeks for a total of 8 weeks

    - Cycle 5 – Cycle 8: You will continue to receive atezolizumab with a different chemotherapy plus trastuzumab and pertuzumab into your vein, which will be given every 3 weeks for a total of 12 weeks
- Group 2:
    - Cycle 1 – Cycle 4: You will be given placebo and chemotherapy into your vein once every 2 weeks for a total of 8 weeks
    - Cycle 5 – Cycle 8: You will continue to receive placebo with a different chemotherapy plus trastuzumab and pertuzumab into your vein, which will be given every 3 weeks for a total of 12 weeks

After completion of these eight rounds of treatment (approximately 20 weeks) you will then have surgery for your breast cancer. After surgery you will receive a further 14 rounds of treatment with:

- Group 1:
    - Cycle 9 – Cycle 22: You will continue to recieve atezolizumab plus trastuzumab and pertuzumab into your vein once every 3 weeks
    - OR, if your cancer has not completely disappeared when you have surgery, you may receive atezolizumab plus trastuzumab emtasine into your vein once every 3 weeks
- Group 2:
    - Cycle 9 - Cycle 22: You will continue to receive placebo plus trastuzumab and pertuzumab into your vein once every 3 weeks
    - OR, if your cancer has not completely disappeared when you have surgery, you may receive placebo plus trastuzumab emtasine into your vein once every 3 weeks

To allow a fair comparison between atezolizumab and placebo, you and your clinical trial doctor will be ‘blinded’ to treatment. This means that neither you nor your clinical trial doctor will know which treatment you are taking. If your safety is at risk, your clinical trial doctor can find out which drug you are being given.

How often will I be seen in follow-up appointments, and for how long? You will be given the trial treatment for approximately 20 weeks before you have your surgery. Then after your sugery you will continue to receive the trial treatment every 3 weeks for a further 14 rounds of treatment. You are free to stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor, approximately every 3 months for 1 year, then every 6 months until the end of the study. These clinic visits will include a physical examination, a pregnancy test if you are a woman, surveys about how you are feeling and managing with day-to-day tasks, and to talk about how your cancer is responding to the treatment and any side effects that you may be having.

What happens if I’m unable to take part in this clinical trial? If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood

tests are not in the range needed for the trial, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/record/NCT03726879

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