

ForPatients

by Roche

Triple Negative Breast Neoplasms Triple Negative Breast Cancer Breast Cancer

Clinical trial of atezolizumab plus chemotherapy compared with chemotherapy alone for patients with recurrent triple-negative breast cancer (IMpassion132)

A Study of the Efficacy and Safety of Atezolizumab Plus Chemotherapy for Patients With Early Relapsing Recurrent Triple-Negative Breast Cancer (IMpassion132)

Trial Status

Active, not recruiting

Trial Runs In

28 Countries

Trial Identifier

NCT03371017 2016-005119-42
MO39193

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 and safety of atezolizumab plus chemotherapy compared with placebo plus chemotherapy in patients with inoperable recurrent triple-negative breast cancer (TNBC).

Hoffmann-La Roche

Sponsor

Phase 3

Phase

NCT03371017 2016-005119-42 MO39193

Trial Identifiers

Eligibility Criteria:

Gender

All

Age

>= 18 Years

Healthy Volunteers

No

How does the IMpassion132 clinical trial work? This clinical trial is recruiting people who have a specific type of breast cancer called 'triple-negative breast cancer' (TNBC), and is testing the cancer immunotherapy, atezolizumab, plus standard chemotherapy. TNBC is a kind of breast cancer that does not have any of the receptors that are often found in breast cancer: oestrogen, progesterone or human epidermal growth factor (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. You must have been diagnosed with TNBC that has spread

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to nearby tissue or lymph nodes, is not removable with surgery, and has come back (recurred) less than 12 months after your previous treatment. You must not have been given certain treatments for your TNBC since it recurred. This clinical trial is now only recruiting people whose tumours have cells showing a protein called PD-L1.

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, including a tumour sample (which may have been taken from a previous surgery or biopsy), blood tests and physical examinations, to make sure that you will be able to take the treatments given in this clinical trial. Some of these tests and 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 potential 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.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be assigned to one of two groups randomly (like flipping a coin) and given one of two different treatments. You will have a 1 in 2 chance of being given each treatment.

This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given a 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.

If you join this clinical trial, you will be given:

- Atezolizumab as an infusion into your vein once every three weeks (on Day 1 of the 21-day cycle), plus chemotherapy as tablets to swallow (twice a day for 14 days, followed by one week off) or as an infusion into your vein (on Day 1 and Day 8 of the 21-day cycle)
- OR placebo as an infusion into your vein once every three weeks (on Day 1 of the 21-day cycle), plus chemotherapy as tablets to swallow (twice a day for 14 days, followed by one week off) or as an infusion into your vein (on Day 1 and Day 8 of the 21-day cycle) .

This is a 'double-blind' clinical trial, which means that 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.

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How often will I be seen in follow-up appointments, and for how long? You will be given the clinical trial treatment (atezolizumab plus chemotherapy, or placebo plus chemotherapy) as long as it can help you and you do not have any side effects. You are free to stop the treatment at any time.

During treatment, you will need to go to the clinical trial site at least every three weeks for the treatment to be given. The clinical trial doctor will also check how your cancer is responding to the treatment and talk about any side effects that you may be having. When the treatment has stopped you will still be seen every three months by the clinical trial doctor for at least 18 months, so they can ask you about any new treatments you are being given.

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

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