

ForPatients

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Neoplasias de mama triple negativoCáncer de mama triple negativoCáncer de mama

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
Completo

Trial Runs In
28 Countries

Trial Identifier
NCT03371017 2016-005119-42
MO39193 RENIS IS003085

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

A Phase III, Randomised, Double-Blind, Placebo-Controlled, Multicentre Study Of The Efficacy And Safety Of Atezolizumab Plus Chemotherapy For Patients With Early Relapsing Recurrent (Inoperable Locally Advanced Or Metastatic) Triple-Negative Breast Cancer

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

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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

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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 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

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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.

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

Trial-identifier: NCT03371017

Inclusion Criteria:

- Histologically confirmed triple negative breast cancer (TNBC) that is either locally recurrent, inoperable and cannot be treated with curative intent or is metastatic
- Documented disease progression occurring within 12 months from the last treatment with curative intent
- Prior treatment (of early breast cancer) with an anthracycline and taxane
- Have not received prior chemotherapy or targeted systemic therapy for their locally advanced inoperable or metastatic recurrence. Prior radiation therapy for recurrent disease is permitted
- Measurable or non-measurable disease, as defined by RECIST 1.1
- Availability of a representative formalin-fixed, paraffin-embedded (FFPE) tumour block (preferred) or at least 17 unstained slides obtained from relapsed metastatic or locally advanced diseases may be submitted, if clinically feasible, with an associated pathology report, if available. If a fresh tumour sample is not clinically feasible, either the diagnosis sample, the primary surgical resection sample, or the most recent FFPE tumour biopsy sample should be used.
- Eastern Cooperative Oncology Group performance status 0-1

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- Life expectancy # 12 weeks
- Adequate haematologic and end-organ function
- Negative human immunodeficiency virus (HIV) test ---Negative hepatitis B surface antigen (HBsAg) test at screening
- Negative total hepatitis B core antibody (HBcAb) test at screening, or positive HBcAb test followed by a negative hepatitis B virus (HBV) DNA test at screening
- The HBV DNA test will be performed only for patients who have a negative HBsAg and a positive HBcAb test.
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening.
- Women of childbearing potential must agree to remain abstinent (refrain from heterosexual intercourse) or use a contraceptive method with a failure rate of #1% per year during the treatment period and for at least 5 months after the last dose of atezolizumab or 6 months after the last dose of capecitabine, whichever is later. In addition, women must refrain from donating eggs during the same time period.
- Men must agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agree to refrain from donating sperm

Inclusion criteria for patients enrolled after the recruitment of all-comers is complete:

- PD-L1-positive tumour status (assessed centrally prior to randomisation), defined as PD-L1 expression on tumour-infiltrating immune cells (IC) of 1% or greater.

Exclusion Criteria:

- Spinal cord compression not definitively treated with surgery and/or radiation, or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for > 2 weeks prior to randomisation
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases.
- Symptomatic or rapid visceral progression
- No prior treatment with an anthracycline and taxane
- History of leptomeningeal disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently) (patients with indwelling catheters such as PleurX® are allowed)
- Uncontrolled tumour-related pain
- Uncontrolled or symptomatic hypercalcemia
- Malignancies other than TNBC within 5 years prior to randomisation)
- Significant cardiovascular disease, within 3 months prior to randomisation, unstable arrhythmias, or unstable angina
- Presence of an abnormal ECG
- Severe infection requiring oral or IV antibiotics within 4 weeks prior to randomisation, including but not limited to hospitalization for complications of infection, bacteraemia, or severe pneumonia.
- Current treatment with anti-viral therapy for HBV.
- Major surgical procedure within 4 weeks prior to randomisation or anticipation of the need for a major surgical procedure during the course of the study other than for diagnosis
- Treatment with investigational therapy within 28 days prior to randomisation
- Pregnant or lactating, or intending to become pregnant during or within 5 months after the last dose of atezolizumab, or within 6 months after the last dose of capecitabine, whichever is later.

Exclusion Criteria Related to Atezolizumab:

- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanised antibodies or fusion proteins

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- Known hypersensitivity or allergy to biopharmaceuticals produced in Chinese hamster ovary cells or to any component of the atezolizumab formulation
- History of autoimmune disease
- Prior allogeneic stem cell or solid organ transplantation
- History of idiopathic pulmonary fibrosis (including pneumonitis), drug-induced pneumonitis, organizing pneumonia (i.e. bronchiolitis obliterans, cryptogenic organizing pneumonia), or evidence of active pneumonitis on screening chest computerised tomography (CT) scan History of radiation pneumonitis in the radiation field (fibrosis) is permitted.
- Active tuberculosis
- Receipt of a live, attenuated vaccine within 4 weeks prior to randomisation or anticipation that a live, attenuated vaccine will be required during atezolizumab/placebo treatment or within 5 months after the last dose of atezolizumab/placebo
- Prior treatment with CD137 agonists, anti-PD-1, or anti-PD-L1 therapeutic antibody or pathway targeting agents
- Treatment with systemic immunostimulatory agents (including but not limited to interferons or interleukin [IL]-2) within 4 weeks or five half-lives of the drug (whichever is longer) prior to randomisation
- Treatment with systemic corticosteroids or other systemic immunosuppressive medications within 2 weeks prior to start of study treatment, or anticipated requirement for systemic immunosuppressive medications during the trial

Exclusion Criteria Related to Capecitabine:

- Inability to swallow pills
- Malabsorption syndrome, disease significantly affecting gastrointestinal function, resection of the stomach or small bowel, or ulcerative colitis
- Known dihydropyrimidine dehydrogenase (DPD) deficiency or history of severe and unexpected reactions to fluoropyrimidine therapy in patients selected to receive capecitabine

Exclusion Criteria Related to Carboplatin/Gemcitabine:

- Hypersensitivity to platinum containing compounds or any component of carboplatin or gemcitabine drug formulations in patients selected to receive carboplatin and Gemcitabine