ForPatients
by Roche

Muscle-invasive Bladder Cancer Bladder Cancer

A clinical trial to compare the effectiveness and safety of atezolizumab with placebo in people with bladder cancer

A Study of Atezolizumab Versus Placebo as Adjuvant Therapy in Patients With High-Risk Muscle-Invasive Bladder Cancer Who Are ctDNA Positive Following Cystectomy

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	24 Countries	NCT04660344 BO42843

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 is a global Phase III, randomized, placebo-controlled, double-blind study designed to evaluate the efficacy and safety of adjuvant treatment with atezolizumab compared with placebo in participants with MIBC who are ctDNA positive and are at high risk for recurrence following cystectomy.

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

NCT04660344 BO42843
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the IMvigor011 clinical trial work?

This clinical trial is recruiting people with a type of bladder cancer called muscle-invasive bladder cancer (MIBC), where the cancer has spread to the muscle layer of the bladder and the bladder has been surgically removed.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab against a placebo (with no active ingredient) in patients with MIBC who have had surgery to remove the bladder with no evidence of cancer on imaging but with confirmed circulating tumour DNA.

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 high-risk MIBC and been successfully treated with surgery to remove the bladder and the cancer within the last 6–14 weeks. A sample of the tumour will be tested for a protein called PD-L1.

If you have received certain treatments in the past, or within a particular timeframe, you may not be able to take part. You must not be pregnant or breastfeeding.

In order to be eligible for the clinical trial treatment, you must first take part in the ‘surveillance phase’ of the study, after which you may be invited to join the ‘treatment phase’.

During the surveillance phase, you will be monitored through regular blood tests every 6 weeks for up to 6 months (until 36 weeks from the date of surgery have passed) and then will continue with blood tests and scans every 12 weeks for up to 21 months. If the blood tests show you have fragments of genetic material from the tumour in your blood (known as circulating tumor DNA [or ctDNA]), and if your scans show no evidence that the bladder cancer has come back, you will be invited to join the treatment phase of the clinical trial. Finding cancer ctDNA in your blood after surgery might mean you are at a higher risk of having the cancer return.

You must have fully recovered from surgery before being allowed to enter the treatment phase.

If no ctDNA is detected in your blood at the end of the surveillance phase, you will not be able to continue in the study. Instead you will receive standard of care treatment outside of the study.

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, women who 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 is eligible to receive treatment will be split into 2 groups and given either:

- Atezolizumab, given as an infusion into the vein every 28 days for up to 12 rounds (1 year) of treatment
- OR placebo (non-active medicine) given as an infusion into the vein every 28 days for up to 12 rounds
  (1 year) of treatment

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 show that any effects (good or bad) are a result of the active treatment being tested and that the doctor or the participants cannot influence the results of the clinical trial.

You will have a 2 in 3 chance of being placed in the atezolizumab group and a 1 in 3 chance of being placed in the placebo group.

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 OR placebo for up to 12 rounds of treatment or up to 1 year (whichever occurs first). You are free to stop this treatment at any time.

During the treatment phase, you will have scans and blood tests every 9 weeks to see how you are responding to treatment and other regular checks for any potential side effects that you may be having.

If you need to leave the trial during treatment, you will be asked to return for a follow-up visit within 30 days of your last dose.

After completing treatment, you will still have scheduled assessments to check for signs of cancer every 9 weeks for the first year, every 12 weeks for the next year and every 24 weeks for the following 2 years, with one final visit after another 48 weeks.

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 **https://clinicaltrials.gov/ct2/show/record/NCT04660344**

Trial-identifier: NCT04660344