ForPatients
by Roche

Hepatocellular Carcinoma (HCC)

A clinical trial to compare atezolizumab plus bevacizumab with active surveillance in people who have been treated for hepatocellular carcinoma (or HCC) through surgery or ablation, but who are at high risk of their HCC coming back.

A Study of Atezolizumab Plus Bevacizumab Versus Active Surveillance as Adjuvant Therapy in Patients With Hepatocellular Carcinoma at High Risk of Recurrence After Surgical Resection or Ablation

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	26 Countries	NCT04102098 2019-002491-14 WO41535

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 adjuvant therapy with atezolizumab plus bevacizumab compared with active surveillance in participants with completely resected or ablated hepatocellular carcinoma (HCC) who are at high risk for disease recurrence.

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

NCT04102098 2019-002491-14 WO41535
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the IMbrave050 clinical trial work? This clinical trial is recruiting people with a type of cancer called hepatocellular carcinoma (or HCC) that was successfully removed through surgery or ablation. In order to take part, patients must be at high risk of their HCC coming back.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus bevacizumab with active surveillance (current standard of care) in patients who

previously had HCC to see which is better at stopping or delaying their HCC from coming back. If you take part in this clinical trial, you will receive either atezolizumab and bevacizumab or you will be placed under active surveillance.

How do i take part in this clinical trial? To be able to take part in this clinical trial, you must have previously had HCC that was successfully removed through surgery or ablation, but be at high risk for your HCC to come back.

You must not have any remaining HCC cells and you cannot join the trial if you are pregnant or breastfeeding.

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 initial 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 either:

- given atezolizumab plus bevacizumab as an infusion into your vein every 3 weeks
- OR placed under active surveillance (you will be seen every 6 weeks for tests and monitoring but will not be given any treatment)

You will have an equal chance of being placed in any group.

If you are placed under active surveillance and your HCC comes back, you may be offered the chance to be treated with atezolizumab and bevacizumab.

How often will i be seen in follow-up appointments, and for how long? You will be given the clinical trial treatment or placed under active surveillance for 12 months (or 17 cycles, whichever occurs first) or until your HCC comes back. If your HCC has not come back at the end of 12 months (or 17 cycles, whichever occurs first), you will be seen every 12 weeks until your HCC comes back. You are free to leave this clinical trial at any time. If your HCC comes back, you will still be contacted regularly by the clinical trial doctor every 12 weeks. These checks will assess your general wellbeing and will see if you are being given other treatments for HCC.

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/NCT04102098

Trial-identifier: NCT04102098