

Renal Cell Cancer (RCC) Renal Cell Carcinoma

A clinical trial to compare atezolizumab plus cabozantinib with cabozantinib alone in people with kidney cancer after checkpoint inhibitor treatment has not worked.

A Study of Atezolizumab in Combination With Cabozantinib Compared to Cabozantinib Alone in Participants With Advanced Renal Cell Carcinoma After Immune Checkpoint Inhibitor Treatment

Trial Status
Active, not recruiting

Trial Runs In
15 Countries

Trial Identifier
NCT04338269 WO41994

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 Phase III, multicenter, randomized, open-label study designed to evaluate the efficacy and safety of atezolizumab given in combination with cabozantinib versus cabozantinib alone in participants with inoperable, locally advanced, or metastatic renal cell carcinoma (RCC) who experienced radiographic tumor progression during or after Immune Checkpoint Inhibitor (ICI) treatment in the metastatic setting.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT04338269 WO41994
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
≥18 Years

Healthy Volunteers
No

How does the CONTACT-03 clinical trial work?

This clinical trial is recruiting people who have a type of kidney cancer called renal cell carcinoma. In order to take part, patients must have renal cell carcinoma that has spread

to other parts of the body (locally advanced or metastatic) or cannot be removed by surgery (inoperable).

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus cabozantinib versus cabozantinib alone on patients with renal cell carcinoma. In this clinical trial, you will get either atezolizumab plus cabozantinib or cabozantinib alone.

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 locally advanced or metastatic renal cell carcinoma that has previously been treated with an immune checkpoint inhibitor (such as atezolizumab, avelumab, pembrolizumab, or nivolumab).

You must not have previously received treatment with cabozantinib.

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, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse, or use medically accepted methods of birth control for safety purposes.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Atezolizumab given as an infusion into the vein every 3 weeks and cabozantinib given as tablets to take by mouth every day.

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- OR cabozantinib alone given as tablets to take by mouth every day.

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

Although neither you nor your clinical trial doctor can choose which group you are in, you and your doctor will know which treatment(s) you are receiving.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment for as long as it can help you. You are free to stop this treatment or the study at any time. While being given treatment, you will be seen regularly by the clinical trial doctor. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After you have completed your treatment, you will still be contacted by the clinical trial doctor every 3 months, either in person or over the phone.

What happens if I do not qualify for 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/NCT04338269>

Trial-identifier: NCT04338269