

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 information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.*

**Official Title:**

A Phase III, Multicenter, Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Atezolizumab Given in Combination With Cabozantinib Versus Cabozantinib Alone in Patients With Inoperable, Locally Advanced, or Metastatic Renal Cell Carcinoma Who Experienced Radiographic Tumor Progression During or After Immune Checkpoint Inhibitor Treatment

**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

# ForPatients

*by Roche*

**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.
- 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

### ***Inclusion Criteria:***

- Histologically confirmed locally advanced or metastatic clear cell or non-clear cell (papillary, chromophobe, and unclassified only) RCC. RCC with sarcomatoid features is allowed. Patients with the chromophobe subtype of non-clear cell RCC must have sarcomatoid differentiation.
- Radiographic disease progression to prior ICI therapy for RCC. Patients who experienced radiographic tumor progression during or within 6 months after the last dose of adjuvant ICI are also eligible. ICI is defined by anti-PD-L1 or anti-PD1 antibody including atezolizumab, avelumab, pembrolizumab, durvalumab, or nivolumab. Only patients for whom the immediate preceding line of therapy was an ICI are allowed.
- Measurable disease per RECIST v1.1
- Evaluable IMDC risk score
- Archival tumor specimen, and pretreatment tumor tissue from fresh biopsy at screening, if clinically feasible. Both archival and fresh samples are preferred.
- KPS score of  $\geq 70$
- Recovery to baseline or Grade  $\leq 1$  NCI CTCAE v5.0 from toxicities related to any prior treatments, unless adverse events are clinically nonsignificant and/or stable in the opinion of the investigator. Grade 2 alopecia is allowed for study participation
- Adequate hematologic and end-organ function
- Negative HIV test at screening
- Negative hepatitis B testing at screening
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception and agreement to refrain from donating eggs

- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm

## ***Exclusion Criteria:***

- Treatment with anti-cancer therapy within 14 days prior to initiation of study treatment
- Patients received cabozantinib at any time prior to screening
- Patients who received more than one ICI treatment in the locally advanced or metastatic setting
- Patients who received more than two prior lines of therapy in the locally advanced or metastatic setting
- Patients who have received a mammalian target of rapamycin (mTOR) inhibitor in any setting
- Symptomatic, untreated, or actively progressing CNS metastases
- History of leptomeningeal disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Uncontrolled or symptomatic hypercalcemia or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy or denosumab
- History of malignancy other than renal carcinoma within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Radiotherapy for RCC within 14 days prior to Day 1 of Cycle 1
- Active tuberculosis
- Major surgical procedure, other than for diagnosis, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after final dose of atezolizumab and 4 months after final dose of cabozantinib
- Severe infection within 4 weeks prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia, or any active infection that, in the opinion of the investigator, could impact patient safety
- Pharmacologically uncompensated, symptomatic hypothyroidism
- Uncontrolled hypertension defined as sustained blood pressure >150 mm Hg systolic or > 90 mm Hg diastolic despite optimal antihypertensive treatment (all countries except France); sustained BP > 140 mmHg systolic or > 90 mmHg diastolic despite optimal antihypertensive treatment (France only)
- Significant cardiovascular disease (such as New York Heart Association Class II or greater cardiac disease, unstable arrhythmia, or unstable angina) within 3 months prior to initiation of study treatment
- Significant vascular disease (e.g., aortic aneurysm or arterial dissection requiring surgical repair or recent peripheral arterial thrombosis) within 6 months prior to Day 1 of Cycle 1
- History of congenital QT syndrome
- History or presence of an abnormal ECG that is clinically significant in the investigator's opinion
- Concomitant anticoagulation with coumarin agents (e.g., warfarin), direct thrombin inhibitor dabigatran, direct factor Xa inhibitor betrixaban, or platelet inhibitors (e.g. clopidogrel)