ForPatients
by Roche

Renal Cell Carcinoma

A clinical trial to compare how well different combinations of drugs called immune checkpoint inhibitors work with axitinib in people with previously untreated kidney cancer (renal cell carcinoma) that has spread and cannot be removed with surgery

A Study of Immune Checkpoint Inhibitor Combinations With Axitinib in Participants With Untreated Locally Advanced Unresectable or Metastatic Renal Cell Carcinoma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	9 Countries	NCT05805501 BO43936

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, safety, and pharmacokinetics of tobemstomig (also known as RO7247669) in combination with axitinib alone or with tiragolumab (anti-TIGIT) and axitinib, as compared to pembrolizumab and axitinib in participants with previously untreated, unresectable locally advanced or metastatic clear-cell renal cell carcinoma (ccRCC).

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT05805501 BO43936
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the BO43936 clinical trial needed?

Renal cell carcinoma (RCC) is the most common form of kidney cancer. It is a disease in which cancer cells are found in the lining of the tubes in the kidney. RCC that is ‘locally advanced unresectable’ means the cancer has grown outside of the kidneys and is

not removable by surgery, but it has not spread to other parts of the body. RCC that is ‘metastatic’ means the cancer has spread to other body parts.

Treatments for RCC have improved in recent years. However, new treatments are needed for people with locally advanced or metastatic RCC.

The standard first treatment that is approved in a number of countries for people with locally advanced or metastatic RCC is pembrolizumab given together with axitinib. Pembrolizumab is a type of medicine called an ‘immune checkpoint inhibitor’, or ICI, that helps your immune system to fight cancer. Axitinib is a type of medicine called a tyrosine kinase inhibitor, or TKI, that works by killing cancer cells.

2. How does the BO43936 clinical trial work?

This clinical trial is recruiting people who have renal cell carcinoma (RCC). People can take part if their RCC is untreated and has spread to nearby cells (locally advanced) and cannot be removed with surgery (unresectable), or that has spread to other parts of the body (metastatic).

The purpose of this clinical trial is to compare the effects, good or bad, of combinations of ICIs given with TKIs against the standard ICI/TKI treatment in people with RCC. Participants will either be given:

- Tobemstomig (an ICI) with **axitinib** (a TKI), or
- Tobemstomig with **tiragolumab** (an ICI) and **axitinib**
- The standard treatment **pembrolizumab** with **axitinib**

Participants will be given the clinical trial treatment regularly until the RCC worsens, they have unacceptable side effects, or they have completed 35 rounds of treatment (also called ‘cycles’). Each treatment cycle lasts for 3 weeks.

Participants will be seen by the clinical trial doctor regularly. These hospital visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. After the final dose of treatment, follow-up information will be collected every 3 months for as long as participants agree to it or until the trial ends. This will be via telephone calls, participant medical records or clinic visits. Participants’ total time in the clinical trial will be approximately 2 years. Participants are free to stop trial treatment and leave the clinical trial at any time.

Participants will be allowed to continue with the treatment they receive in the trial beyond 35 cycles if they will benefit from continuing treatment.

3. What are the main endpoints of the BO43936 clinical trial?

The main clinical trial endpoints (the main results that are measured in the trial to see if the medicine has worked) are:

1) The length of time participants live without their cancer worsening (progression-free survival, or PFS)

2) The number and seriousness of any side effects that occur while on the clinical trial treatment

The other clinical trial endpoints include:

- How long people live (overall survival, or OS)
- The number of people whose cancer responds to treatment (overall response rate, or ORR) and
- How long the response to treatment lasts (duration of response, or DOR)

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years of age, have been diagnosed with locally advanced unresectable or metastatic RCC and have not previously been given treatment for RCC.

People may not be able to take part in this trial if they have RCC that has spread to the brain and/or spinal cord, if they have certain other medical conditions, or have previously received certain treatments. Women cannot take part in this trial if they are pregnant, breastfeeding or planning to become pregnant.

5. What treatment will participants be given in this clinical trial?

This is an open-label, randomised trial. Open-label means that everyone involved, including the participants and the doctors, knows which clinical trial drug is being used. Participants will be randomly assigned (by chance) to one of the following three treatment groups (also called treatment ‘arms’) and will be given:

Arm A:

- Tobemstomig given as infusions into the vein every 3 weeks for approximately 2 years
- **Axitinib** given as oral tablets twice a day for approximately 2 years

or

Arm B:

- Tobemstomig given as infusions into the vein every 3 weeks for approximately 2 years
- **Tiragolumab** given as infusions into the vein every 3 weeks for approximately 2 years

- **Axitinib** given as oral tablets twice a day for approximately 2 years

or

Control Arm:

- **Pembrolizumab** given as infusions into the vein every 3 weeks for approximately 2 years
- **Axitinib** given as oral tablets twice a day for approximately 2 years

Participants will have a **1 in 3 chance** of being placed in any of the three treatment arms.

After 35 treatment cycles (approximately 2 years), participants will be allowed to continue treatment with tobemstomig if they are in Arm A or with tobemstomig and tiragolumab if they are in Arm B, if the doctor believes that they will benefit from it.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe and even life-threatening and can vary from person to person.

Tobemstomig, tiragolumab and pembrolizumab

Potential participants will be told about the known side effects of tobemstomig, tiragolumab, and pembrolizumab, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Tobemstomig, tiragolumab, and pembrolizumab will be given via intravenous infusion at a hospital. This involves inserting a needle into a vein to allow the medicine to enter the bloodstream right away. Participants will be told about any known side effects of intravenous infusions.

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Axitinib

Potential participants will be told about the known side effects of axitinib, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Axitinib will be given as oral tablets (given by mouth) to be taken at home, and participants will be told about any known side effects of oral administration.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov