

LITESPARK 024

ONCOLOGY CLINICAL TRIALS

A Clinical Trial for Renal Cell Carcinoma

In this brochure, you will learn about **renal cell carcinoma (RCC)** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational trial drug alone and in combination with another investigational trial drug is safe and may help slow down or stop your RCC from spreading to other areas of the body. You can also use this brochure to talk with your doctor about this trial.

What is Renal Cell Carcinoma?

Renal cell carcinoma (RCC) is the most common type of kidney cancer, which is a cancer that starts in the kidney. It is also called renal cell cancer or renal cell adenocarcinoma.

RCC usually grows as a single tumor in 1 kidney, but sometimes as 2 or more tumors in 1 kidney, or tumors in both kidneys at the same time.

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What are my treatment options?

If you have RCC your care team will talk about your treatment options with you and those close to you. Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if the cancer has spread and how far
- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms


Your care team may offer you 1 or more of these treatments:

Local therapies - treatment directed at the site of the cancer to destroy it

Targeted therapy - treatment that works on specific cells to stop them from growing

Immunotherapy - medicines that help your immune system fight the cancer





Chemotherapy – medicine to kill cancer cells or stop them from growing

Radiation therapy – treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. This would only be used to treat symptoms related to tumor growth.

Palliative care – also called comfort care. This is special care to help ease pain and symptoms with a focus on the person's quality of life. This does not directly treat RCC, but it helps keep you as comfortable as possible.

Clinical trials, such as this one

Talk to your doctor to find out which treatment is right for you.

What is a clinical trial?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

All about this clinical trial

What is the goal of this clinical trial?

The goal of this trial is to learn if the investigational trial drugs Belzutifan (MK-6482) taken alone and in combination with and Palbociclib:


- May help slow down or stop the growth of your RCC
- Are safe when belzutifan (MK-6482) is taken alone or in combination with palbociclib

Researchers will also try to find the recommended dose of belzutifan plus palbociclib.

What treatment is being studied?

Belzutifan is an experimental drug. It has been approved by some health authorities for treating some types of cancer, including RCC in adults with a rare disease called von Hippel-Lindau (VHL). It may not be approved in your country for your type of cancer.

Palbociclib is an experimental drug for the treatment of advanced RCC. It has been approved in some countries for the treatment of some types of breast cancers. It may not be approved in your country.

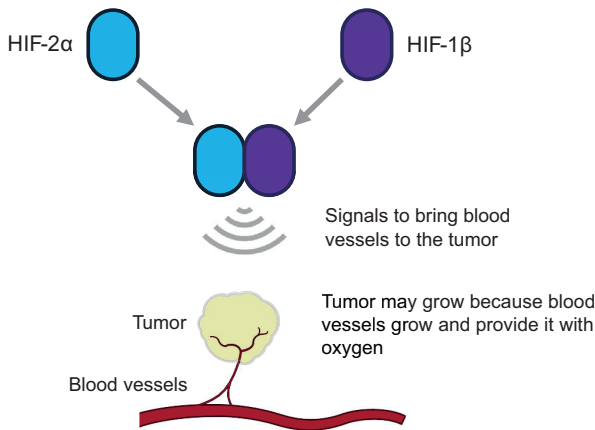


About Belzutifan:

Belzutifan (also known as MK-6482) is an investigational trial drug that may help shrink cancer cells. Belzutifan is approved in some countries to treat some types of RCC.

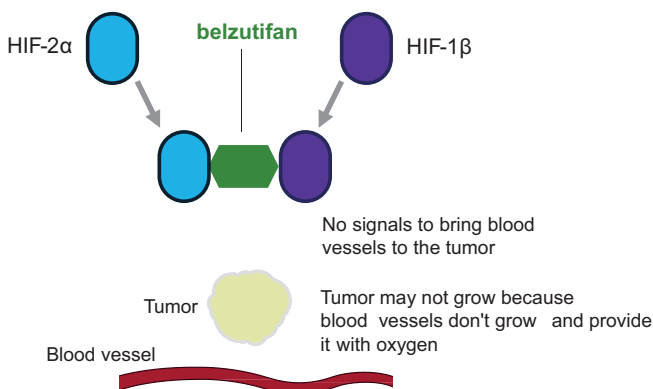
1. The hypoxia-inducible factor, HIF-2 α , is believed to play a critical role in tumor creations and tumor progression in cancers such as PPGL and Renal Cell Carcinoma.
2. When the body experiences hypoxia (low oxygen), HIF-2 α and HIF-1 β can bind together and cause the increased creation of red blood cells and blood vessels that go to the tumor and help it grow. This also may prevent the cell from naturally dying on its own.
3. The investigational trial drug Belzutifan comes in and may help stop HIF-2 α and HIF-1 β from binding to each other.
4. This study is evaluating whether blocking the binding will allow the cell to naturally go through its lifecycle, die off and may cause the tumor cells to stop growing.

Another way to think about Belzutifan



When HIF-2 α and HIF-1 β bind together, it brings oxygen and blood to tumor cells. This helps cancer cells grow and survive.





This clinical trial looks at whether Belzutifan can block HIF-2α and HIF-1β from binding, so that the cancer cells don't get oxygen and blood.

Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation. For example, you must have RCC that was treated before and has gotten worse.

Your trial staff will do tests to see if you are able to join this trial.

You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- How well you tolerate the study treatments



Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the investigational trial drugs are working for you. During your trial visits, you may get:

- Your trial treatments
- Blood and urine tests
- Physical exams
- Imaging scans such as CT scans or MRIs (scans that help the doctor see the cancer inside your body)

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the study treatment works over time.

What treatments will I get?

The drug(s) you get will depend of what group you are assigned to:

Group	Treatment	Chance of being in this group
Group 1	Belzutifan (taken every day) plus palbociclib (taken every day for 21 days, then stopped for 7 days)	2 out of 3
Group 2	Belzutifan (taken every day)	1 out of 3

Belzutifan and palbociclib are tablet that are taken by mouth.

A computer will decide which group you are put in.

You, your trial doctor, and the trial staff will know what treatments you are getting.





To learn more

To learn more about this trial, you can

- Talk to your doctor
- Contact Merck by
 - o Visiting **www.merckoncologyclinicaltrials.com**
 - o Scanning this QR code:

