INTerpath

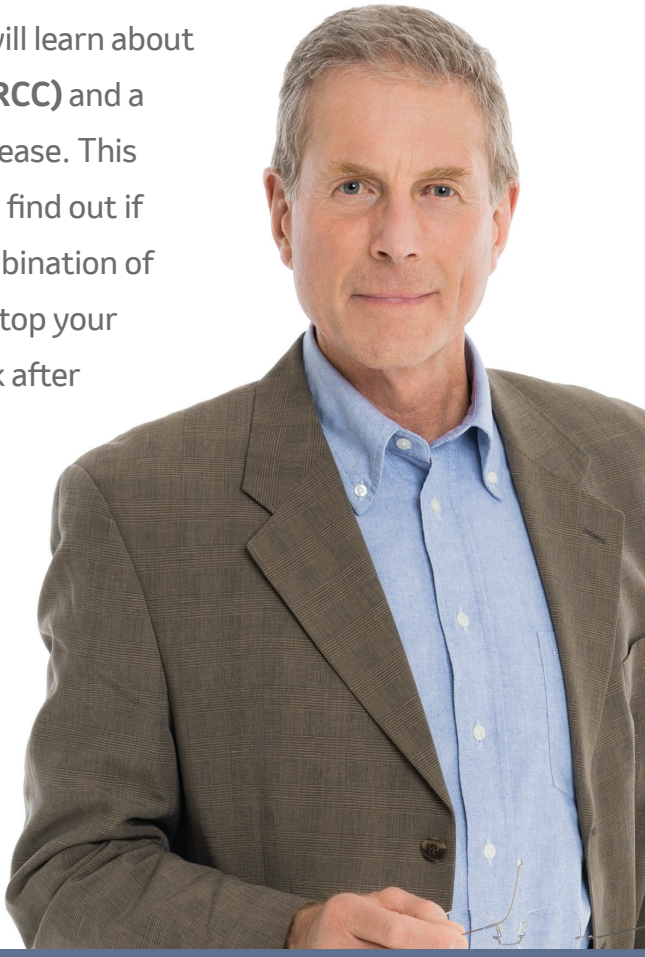
ONCOLOGY CLINICAL TRIALS

# INTerpath 004

## A clinical trial for people with **renal cell carcinoma (RCC)**

In this brochure, you will learn about **renal cell carcinoma (RCC)** and a clinical trial for this disease. This clinical trial is trying to find out if an investigational combination of study drugs can help stop your RCC from coming back after surgery to remove it.

This brochure will help you learn more about RCC and this clinical trial.



## What is Renal Cell Carcinoma (RCC)

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.

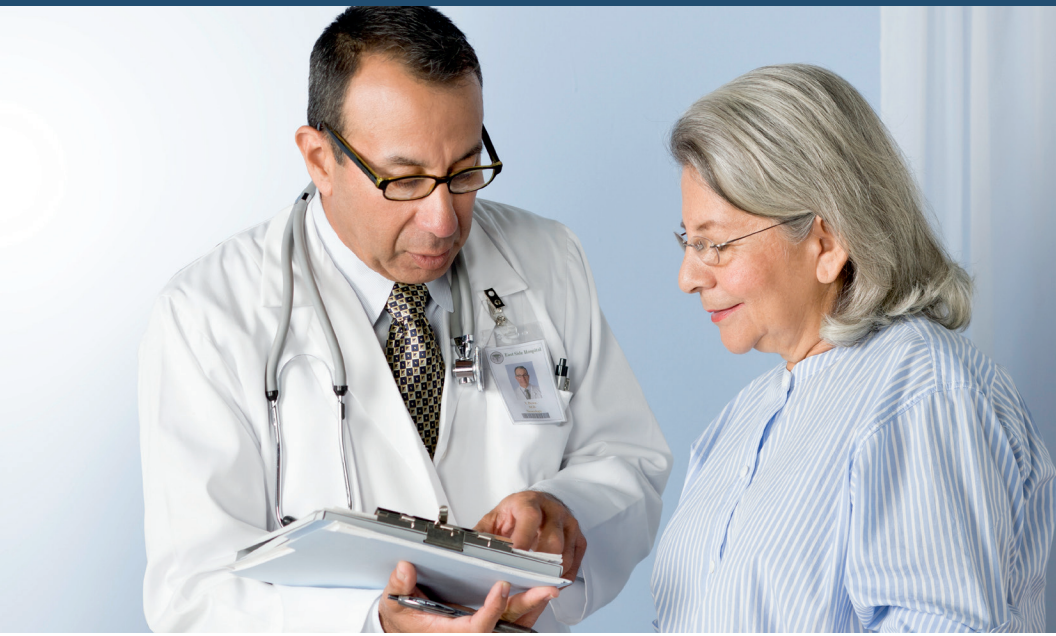
## What are my treatment options?

People with RCC often have surgery to remove the cancer. After surgery, people who have a high chance of cancer coming back get more treatment. For example, pembrolizumab (one of the study drugs) is a treatment given after surgery to prevent or delay RCC from coming back.

If you have RCC, your care team will talk about your treatment options with you and those close to you.

## Your care team may offer you one or more of these options:

- **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



Your options will depend on a few things:

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

Talk to your doctor about 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 theycan 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.

## What is the goal of this trial?

The goal of this trial is to learn if the investigational combination of study drugs, V940 and pembrolizumab:

- Can prevent or delay RCC from coming back after surgery to remove it
- And are safe to use

Researchers will compare the investigational study drug V940 and pembrolizumab to placebo and pembrolizumab (A placebo looks like the study drug but has no active ingredients).

## About V940

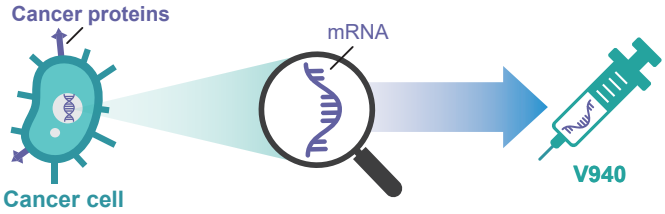
VV940 is a cancer therapy that has not been approved.

1. Every person's cancer has different mutations (changes) in their genes.V940 is made specifically for each person based on their gene mutations – in other words, it is individualized for each person.
2. Before a person gets V940, researchers identify their cancer mutations. They then make mRNA to use in a dose of V940 made just for them (mRNA is genetic material that tells your body how to make proteins). The mRNA makes proteins that look like the person's specific cancer mutations.
3. When the person gets V940 as an injection into their muscles, the mRNA tells their body to make proteins that look like their cancer mutations.
4. These proteins may help the immune system recognize and attack cancer cells with these mutations.

# Another way to think about V940

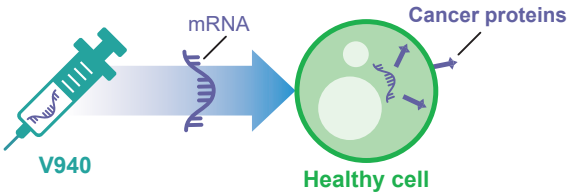
**1**

Researchers find gene mutations unique to a person's **cancer cells** that make **cancer proteins**. They then use these genes to make mRNA for **V940** that is unique to a person's cancer.



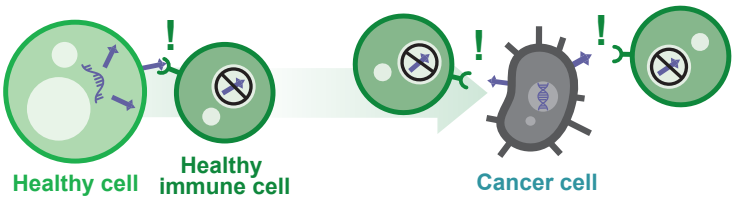

**2**

When **V940** gets in **healthy cells** in the body, the cells use the mRNA to make proteins like the **cancer proteins**.




**3**

The **cancer proteins** from the **healthy cells** may train **healthy immune cells** to find and attack the **cancer cells**.



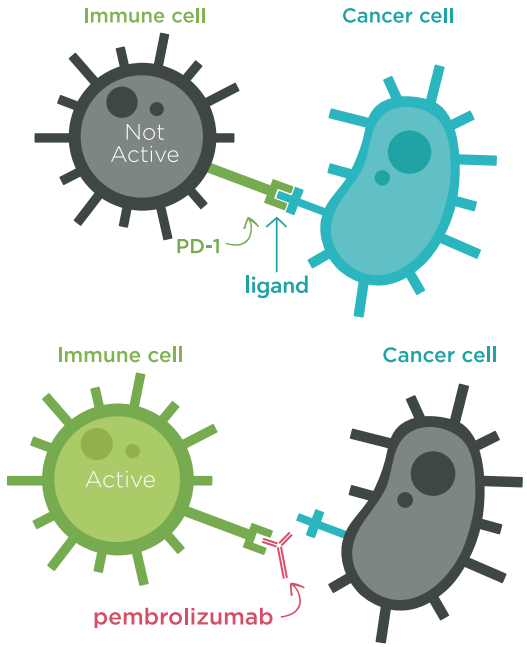
## About pembrolizumab

Pembrolizumab (also known as MK-3475) is a type of immunotherapy, which may help your body's immune system attack cancer cells. Pembrolizumab is already a treatment doctors give after surgery to prevent RCC from coming back.

## Here's how pembrolizumab works:

1. A protein called PD-1 (on some of your immune system cells) sometimes binds with certain molecules called ligands (on some cancer cells)
2. When these bind, it turns off the immune system cell, which means it can't do its work to help protect you and attack cancer cells
3. This is where pembrolizumab comes in - this study drug binds with PD-1 and blocks PD-1 from binding with ligands
4. By blocking PD-1 from binding with ligands, pembrolizumab may help the immune system stay on so it can find and attack cancer cells

## Another way to think about pembrolizumab



## Can I join this trial?

Trial staff will do tests to see if you meet the requirements to be able to join the trial. For example, you must have had surgery to remove RCC. There are additional eligibility criteria that will determine if you will qualify for participation.

You and your trial doctor will discuss:

- All the requirements to decide if this trial is a good option for you
- Possible benefits and risks of being in this trial

Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together.

## If I join, which treatment will I get?

The investigational combination of study drugs you get will depend on which group you are placed in. Regardless of which group you are in, you will receive pembrolizumab.

A computer will randomly decide which group you are put in. You will have an equal chance of being in 1 of 2 groups:

- **Group 1:** You will get **V940** and **pembrolizumab**
- **Group 2:** You will get the **placebo** and **pembrolizumab**

You will get pembrolizumab:

- Through an IV (needle in your vein)
- Once every 6 weeks for 9 doses (over about 1 year and 2 months)
- For as long as you are able to tolerate it

You will get V940 or the placebo:

- As a shot (injection) in a muscle in your shoulder, thigh, or bottom
- Once every 3 weeks for a total of 9 doses (over about 7 months)
- For as long as you are able to tolerate it

You, your trial doctor, and the trial staff won't know which group you are in and which treatment you are getting. But in case of a health emergency, they can find out.

## If I join, 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 trial drugs are working for you. During your trial visits, you may get:

- The trial drugs
- Blood tests
- Physical exams
- Survey questionnaires
- Imaging scans, such as CT scans, MRIs, and bone scans

## If you join the trial, your doctor will need to contact you even after your trial visits are over.

This is very important because this clinical trial is studying how well the trial treatments work over time.

### Thank you for learning about RCC and this clinical trial.

**Your questions and notes:**

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## To learn more

Talk to your study doctor or contact: