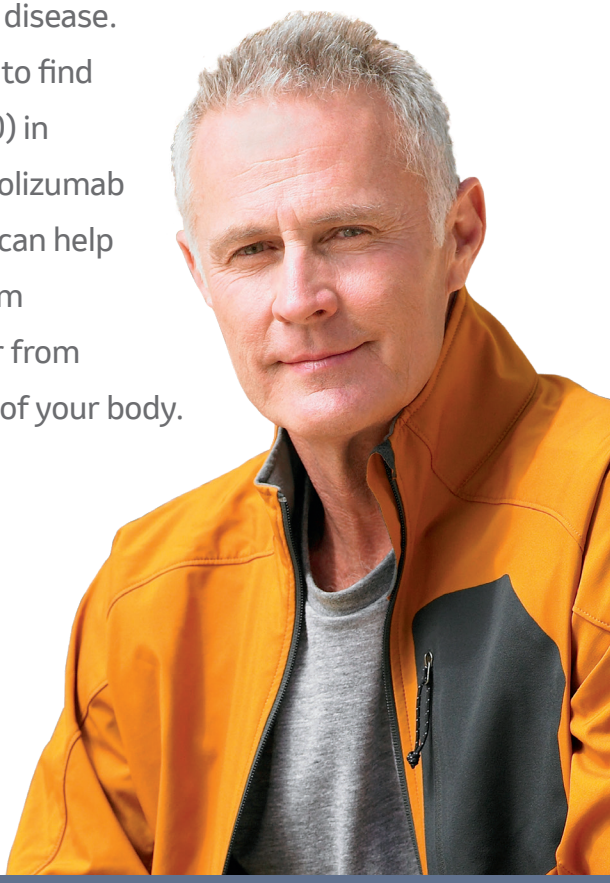
INTerpath

ONCOLOGY CLINICAL TRIALS

V940-007

A clinical trial
cutaneous squamous cell carcinoma (cSCC)

In this brochure, you will learn about **cSCC** and a clinical trial for this disease. This clinical trial is trying to find out if a study drug (V940) in combination with pembrolizumab or pembrolizumab alone can help stop your skin cancer from growing, coming back, or from spreading to other areas of your body.



What is cSCC?

cSCC is the second most common type of skin cancer. Exposing your skin to the sun and its ultraviolet (UV) light from the sun is the most common risk factor for cSCC. A risk factor is anything that raises the chance of developing a disease.

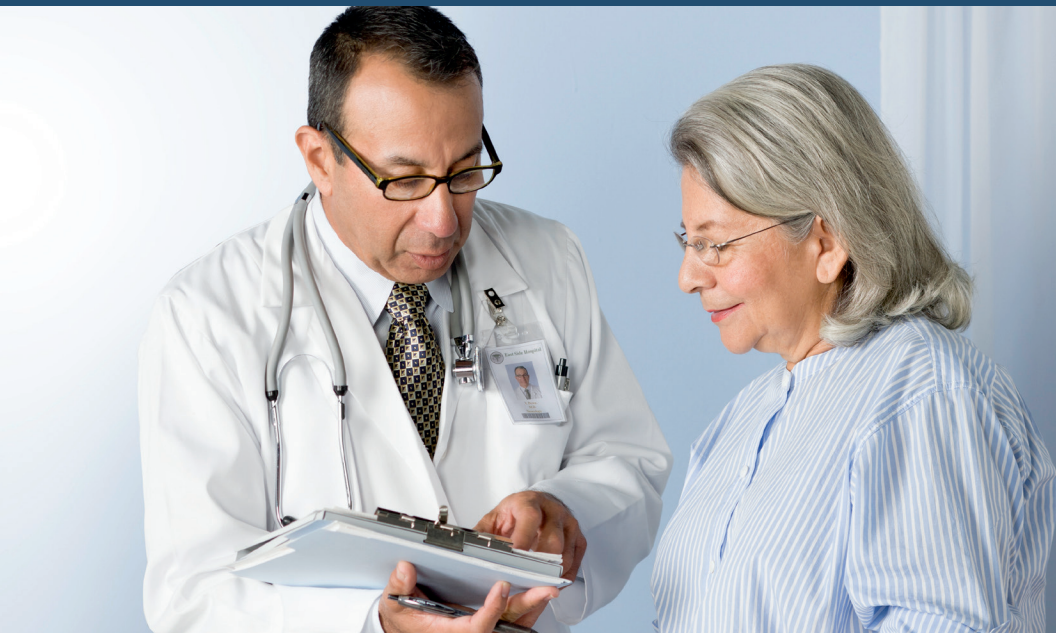
The usual treatment (or standard treatment) for cSCC is to remove the cancer with surgery and radiation therapy, if needed. However, even if a doctor removes cSCC with surgery, it could come back or spread to other parts of the body.

Your treatment options

- If you have cSCC, your cancer care team will discuss your treatment options with you and those close to you. Your options will depend on several things including: The thickness of your skin cancer lesion (growth or mark on the skin) and where it is on your body
- Your symptoms from the cancer including whether your lesion is bleeding, if it has an ulcer (an open sore on the skin), or affecting a nearby organ such as the eyelid, nose, ear etc.
- The stage of your cancer, which tells you how big it is and if it has spread to local surrounding tissues/glands, or spread to a different site(s) in the body
- Whether your cancer be completely removed by surgery, without severe damage to your normal organs/tissue
- Your overall age and health

Your care team may offer you one or more of these options, depending on the stage of your cancer:

- **Local therapies** – treatment directed at the site of the cancer to destroy it or remove it (surgery)
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing/spreading further



- **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 cSCC but it helps keep you as comfortable as possible.
- **Clinical trials**, such as this one

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 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

Why is this study being done?

This trial is trying to find out if a study drug (V940 in combination with pembrolizumab) is safe and works to shrink the tumor and prevent it from coming back or spreading to other areas of the body, after surgery and radiation (if needed) to remove the cSCC. Researchers will also see what side effects may happen and how manageable they are.

Who can join this trial?

You may be able to join this clinical trial if:

- You have cSCC
- Your cancer is resectable (it is possible for the cancer to be removed completely by surgery)
- The cancer has not spread to other parts of your body
- You have not had previous systemic treatments for your cancer. Systemic treatments are anti-cancer drugs that spread through the body to treat cancer cells wherever they are.
- You must be able to provide a tissue sample of your cancer and a blood sample, before entry into the trial.
- Your doctor does tests to confirm you are healthy enough to join the study

You and your doctor will also talk about the possible benefits and risks of joining.

What treatments are being studied?

The study drug is called **V940** (also known as mRNA-4157).

The treatments being studied are:

- Combination of V940 (the study drug) with pembrolizumab, both of which are types of immunotherapy
- Pembrolizumab alone
- Standard of care treatment, which is surgery to remove the skin cancer (and radiation if needed)

Immunotherapy is a treatment that works with a person's immune system to fight disease, including some cancers.

If I join, what treatment will I get?

You will be randomly assigned to 1 of the 3 groups. The treatment you get will depend on which group you are placed in.

Group	Treatment before surgery	Surgery to remove the cancer	Treatment after surgery
Group A: V940 with pembrolizumab and standard of care treatment	• V940 – up to 2 doses (3 weeks apart) • Pembrolizumab – 2 doses (6 weeks apart)	Yes	• V940 – 7 doses (3 weeks apart) • Pembrolizumab – 9 doses (6 weeks apart)
Group B: Standard of care treatment (surgery, and radiation if needed)	None	Yes	None
Group C: Pembrolizumab and standard of care treatment	Pembrolizumab – 2 doses (6 weeks apart)	Yes	Pembrolizumab – 9 doses (6 weeks apart)

Here is what researchers know or assume about how each study drug works on its own.

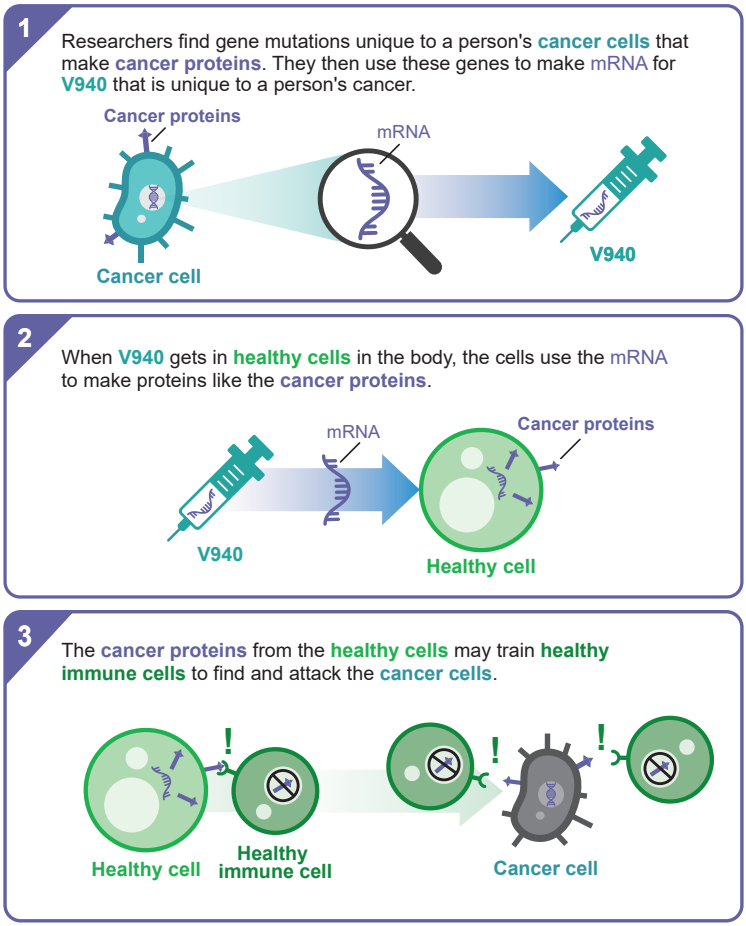
How does V940 work?

V940 is a cancer therapy that has not been approved.

1. Every person's cancer has different mutations (changes) in their genes. This is why some medicines may not work for all people even if they have the same type of cancer. V940 is called an 'mRNA' individualized therapy, and is made specifically for each person based on their gene mutations – in other words, it is personalized for each individual.

2. Before a person gets V940, researchers find their cancer mutations in a tissue sample taken from their tumor. 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 looks like their cancer mutations.
4. These proteins may train their immune system to better find and destroy cancer cells with these mutations.

Another way to think about V940

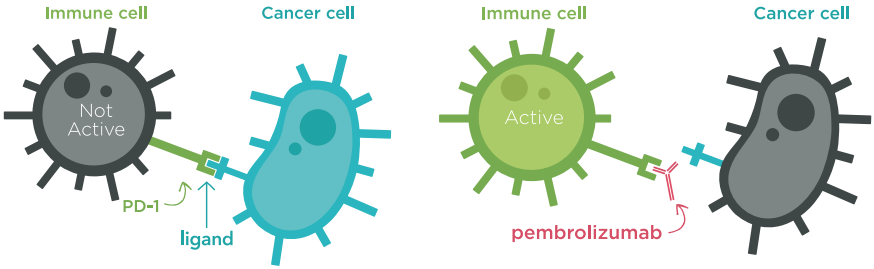


How does pembrolizumab work?

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

When PD-1 and ligands bind, it's like turning off the immune cell. This means that the immune cell will not do its work to attack cancer cells.



If I join, what will happen during trial visits?

You will visit the trial site on a regular schedule so that your doctors can see how the trial drug is working for you. During your trial visits, you might get:

- Blood tests
- Physical exams
- Trial drugs
- Imaging scans, such as CT scans or MRIs
- Digital photographs
- Surgery
- Radiation (if needed)
- New biopsy (if needed)

What happens when the trial is over?

If you join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is called the follow-up period. This is very important because this clinical trial is studying how well the trial drugs work overtime.

Your questions and notes:

To learn more

Talk to your study doctor or contact:

www.merckclinicaltrials.com