INTerpath

ONCOLOGY CLINICAL TRIALS

INTerpath 002

A clinical trial for **Early-Stage Non-Small Cell Lung Cancer (NSCLC)**

In this brochure, you will learn about **early-stage NSCLC** and a clinical trial for this disease. This clinical trial is trying to find out if an investigational combination of study drugs may help stop your early-stage NSCLC from coming back after having surgery to remove the cancer or from spreading to other areas of your body.

What is Early-Stage NSCLC

NSCLC is a fast-growing cancer that starts in your lungs and can spread to other organs. It is the most common type of lung cancer - about 8 out of 10 lung cancers are NSCLC.

Lung cancer develops when cells of the lung become abnormal and begin to grow out of control. As more cancer cells develop, they can form into a tumor. Tumors may spread to other areas of the body.

There are two main types of lung cancer: non-small cell lung cancer and small cell lung cancer. Not all lung cancers are treated the same way. Depending on the stage, type and molecular testing results for your cancer, the doctor will determine what treatment options are best for you.

This trial is studying an investigational combination of study drugs in people with early-stage NSCLC after surgery has been performed to remove their cancer.

Your treatment options

If you have early-stage NSCLC, your cancer care team will discuss your treatment options with you and those close to you. Your options will depend on many things including:

- The type of NSCLC you have
- The stage of your cancer, which tells you if it has spread and if so, how far
- Your overall health
- Chance of the cancer coming back
- Side effects you may have from the treatment
- What chance the treatment has of reducing or removing the disease
- How long the treatment might help extend your life

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

- **Surgery** – removal of all or part of the cancer
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing
- **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, 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

Why is this study being done?

This trial is trying to find out if an investigational combination of study drugs is safe and may help to prevent early-stage NSCLC from coming back or spreading to other areas of the body in patients with Stage II-to-IIIB NSCLC after having surgery to remove the cancer. Researchers will also see what side effects may happen.

Who can join this trial?

There are certain rules and tests you must meet to join one of these trials, such as being diagnosed with Stage II-to-IIIB NSCLC. Other rules may include:

- Being able to undergo surgery or recently have had surgery to remove your NSCLC
- Having available tumor tissue
- Other tests to make sure you qualify

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

What treatments are being studied?

This trial is studying an investigational combination of study drugs. The treatments being studied are:

- V940 (also known as mRNA-4157), in combination with pembrolizumab, both of which are types of immunotherapy.
- Placebo with pembrolizumab

Immunotherapy is a treatment that works with a person's immune system to fight disease, including some cancers. A **placebo** is something that looks like the study medicine but has no actual study medicine in it.

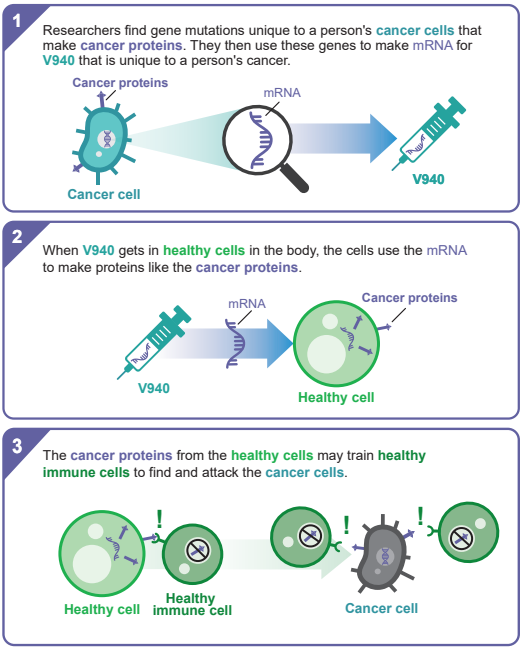
Here is what researchers know or assume about how each study drug works on its own.

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' therapy and is made specifically for each person based on their tumor's gene mutations – in other words, it is personalized for each individual.
2. Before a person gets V940, researchers find the tumor's gene mutations. Researchers 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 muscle, the mRNA tells their body to make proteins that looks like their cancer mutations.
4. These proteins may help their immune system to identify and attack cancer cells with these mutations.

Another way to think about V940

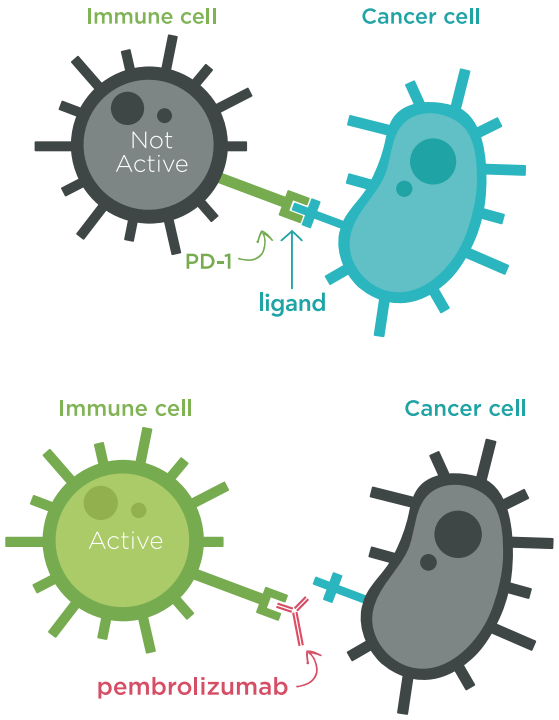


About pembrolizumab:

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 the trial, what treatment will I get?

You will be randomly assigned to 1 of the 2 groups. The treatment you get will depend on which group you are placed in:

- **Group 1** will get V940 (9 doses every 3 weeks) with pembrolizumab (9 cycles every 6 weeks)
- **Group 2:** will get placebo (9 doses every 3 weeks) with pembrolizumab (9 cycles every 6 weeks)

You will have about a:

- 50% chance of being in Group 1, and a
- 50% chance of being in Group 2

Neither you nor your trial doctor will know which group you are in.

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
- Biopsy
- Imaging scans, such as CT scans or MRIs

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 over time.

Thank you for reviewing this information about early-stage NSCLC and this clinical trial.

To learn more

Talk to your study doctor or contact:

www.merckclinicaltrials.com