INTerpath

ONCOLOGY CLINICAL TRIALS

INTerpath 014

A clinical trial for **High-Risk Stage I Non-Small Cell Lung Cancer (NSCLC)**

In this brochure, you will learn about **High-Risk Stage I NSCLC** and a clinical trial for this disease. This clinical trial is trying to find out if an investigational drug given alone or in an investigational combination, when given after surgery, may help prevent NSCLC from coming back or spreading to other areas of the body.

You can also use this brochure to talk with your doctor about this trial.

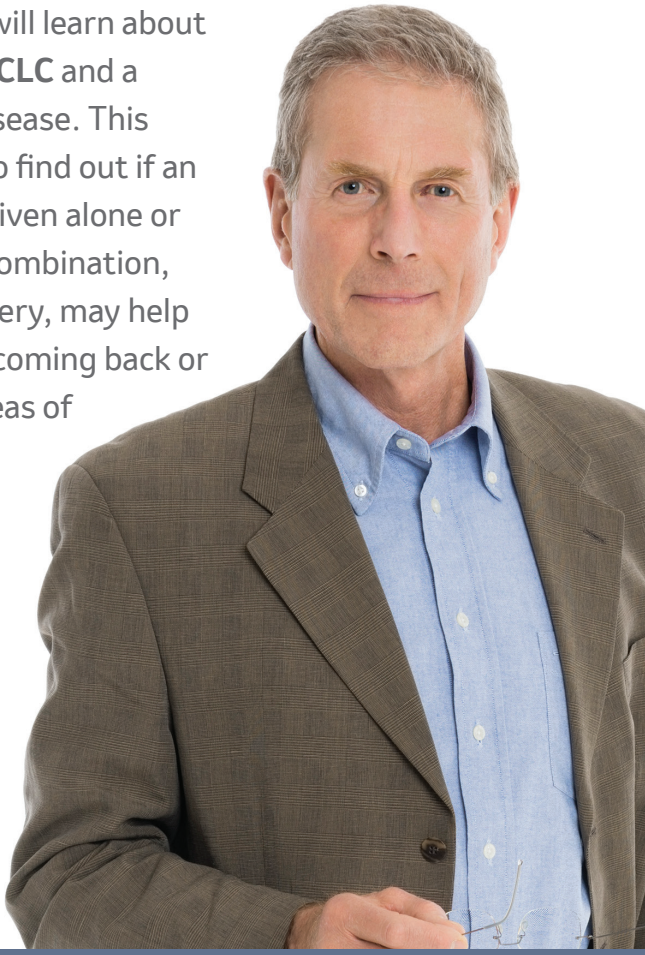


Table of Contents

- What is High-Risk Stage I NSCLC?
  - What are my treatment options?
- What is a clinical trial?
  - All about this clinical trial
  - What is the goal of this trial?
  - What is the study treatment being researched?
  - About V940 (mRNA-4157)
- Who can join this trial?
- If I am able to join, how long will I be in the trial?
- What will happen during trial visits?
- What study treatment will I get?
- What is a tissue sample and why is it part of this trial?
- Notes

What is High-Risk Stage I 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 investigational study drugs in people with high-risk stage I NSCLC after surgery has been performed to remove their cancer.

What are my treatment options?

If you have high-risk stage I NSCLC, your cancer care team will discuss your treatment options with you and those close to you.

Your options will depend on several things:

- Your overall health
- The type of lung cancer you have
- The stage of your cancer, which tells you how far the cancer has spread
- The chance of the cancer coming back
- Side effects you may have from the treatment
- The chance of 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
- Features of your cancer cells (called biomarkers) that may help guide your treatment

Talk to your doctor about which treatment is right for you.

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

- **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.
- **Surgery** - treatment to remove all or part of the cancer
- **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

What is the goal of this trial?

The goal of this trial is to learn if the investigational drug, V940, given alone or in an investigational combination with MK3475A, and given after surgery in high-risk stage I NSCLC, is safe and may help prevent high-risk stage I NSCLC from coming back or spreading to other areas of the body. Researchers will also see what side effects may happen. Researchers will compare V940 given with or without MK-3475A versus placebo. A placebo looks like the investigational medicine but has no active ingredients. Using a placebo may help researchers better understand the real effects of the investigational medicine.

MK-3475A has been approved in the US to treat various types of

cancer, including certain types of NSCLC. It may not be approved in your country for your exact type of cancer. MK-3475A is given as an injection (shot) under the skin. MK-3475A contains 2 drugs: Pembrolizumab (pembro) and Berahyaluronidase alfa (MK-5180). MK-5180 helps the body absorb and distribute drugs like pembro. V940 and MK-3475A are experimental in this trial. V940 has not been approved to treat any type of cancer.

What is the study treatment being researched?

This trial is studying an investigational drug when given alone and in an investigational combination. The study treatments being studied are:

- The investigational combination of V940 (also known as mRNA-4157), with MK-3475A,
- The investigational drug, V940
- Placebo

V940 and the investigational combination of V940 and MK3475A are investigational immunotherapies. An **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. The placebo for this study looks like the investigational drug, V940.

Here is what researchers assume about how each study drug may work on its own.

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.

About V940 (mRNA-4157)

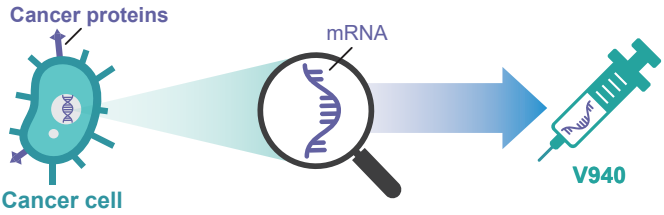
V940 is an investigational drug that has not been approved.

1. Every person's cancer has different mutations (changes) in their genes. V490 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 find 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 looks 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

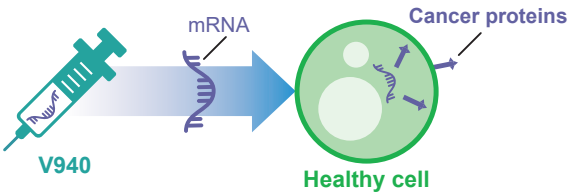
1

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.



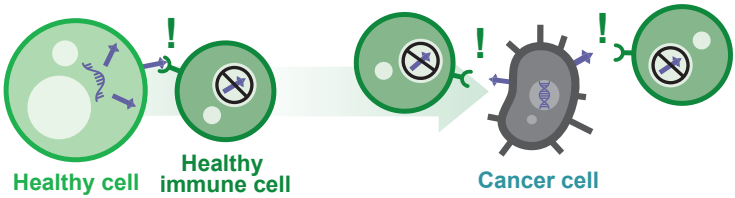
2

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**.

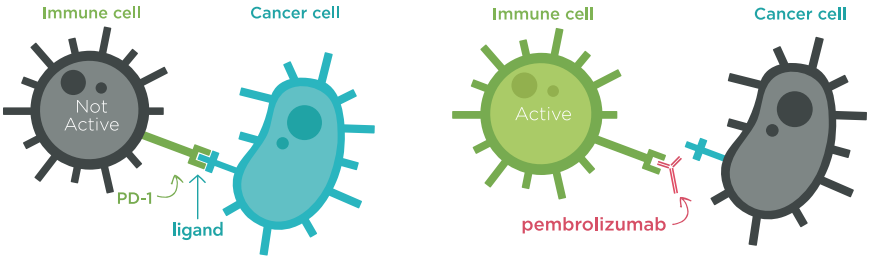


About pembrolizumab

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



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 I 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

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
- What type of cancer you have
- How well you tolerate the study treatments

If you are eligible for trial participation, and you tolerate the study treatments well, you can expect to be in the trial for up to 1 year of treatment and 10 years of follow-up.

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 study drugs are working for you. During your trial visits, you might get:

- Blood and urine (pee) tests
- Physical exams
- Trial drugs
- Imaging scans, such as CT scans or MRIs

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 study treatment will I get?

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

- **Group 1** will get the investigational combination of V940 (9 doses every 3 weeks) with MK-3475A (9 cycles every 6 weeks)
- **Group 2** will get the investigational drug, V940, alone (9 doses every 3 weeks)
- **Group 3** will get placebo alone (9 doses every 3 weeks)

A computer will decide which group you are put in.

If you are assigned to Groups 2 or 3, you, your trial doctor, and the trial staff will not know which study treatments you are getting. In case of an emergency, they can find out.

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 is a tissue sample and why is it part of this trial?

If you are eligible and join the trial, the study doctor will ask you for tissue samples. Tissue, such as skin, hair, nails, blood, urine or tumors, are found in your body and are collected as they may help researchers understand diseases and find ways to help prevent and treat them in people.

For this study, your study doctor will collect tumor and blood tissue samples. These may be new tissue samples, or they may ask to use tissue that was collected before. Tissue you provide

for the study will be stored for research only and will continue to be tracked according to your study code number.

If a new tissue sample is collected for this study, the study doctor will explain how it will be collected and any risks. Some risks include:

- Low blood pressure
- Pain
- Bruising
- Redness
- Swelling
- Scarring
- Infection

There are also risks related to data privacy (please see frequently asked questions below) and the release of personal information from your health records.

Frequently asked questions about tissue collection

Will I find out the results of the research using my tissue?

This will depend on the reason for the tissue sample. You may see the results of your biomarker test (such as a biopsy or blood test) if it is required for you to join, or impacts your current participation in, the clinical trial. Results of tests performed only for research purposes will generally not be provided.

How is my privacy protected?

To protect your privacy, we take steps to limit the risk of anyone identifying you:

- We label your tissue with a number instead of your name
- We remove your name, address, phone number, social security number, date of birth and anything else that could directly identify you before researchers get access to your records or tissue sample.

If I agree to take part in the study, can I change my mind later?

Yes. You can change your mind about taking part in the trial at any time. Here's how:

1. Contact your study doctor and tell them you do not want to be in the study anymore.
2. The study doctor will contact the study Sponsor.

Tissue samples obtained up until the point of you withdrawing from the trial will continue to be retained to support the trial research.

Thank you for learning about NSCLC and this clinical trial.

Your questions and notes:

You can use this space to write down notes or questions about this trial.

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Visit **www.merckoncologyclinicaltrials.com**
- Scan this QR code:

V940-014_PB_NA_English_V00.4_12Dec2025
Copyright © 2026 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.

For more information, contact our research staff: