INTerpath

ONCOLOGY CLINICAL TRIALS

INTerpath-013

Learn about a clinical trial for **Lung Cancer**

In this brochure, you will learn about **non-small cell lung cancer (NSCLC)** and a clinical trial for this disease. This clinical trial is trying to find out if an investigational trial drug combination may help stop or slow down the growth of NSCLC.

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

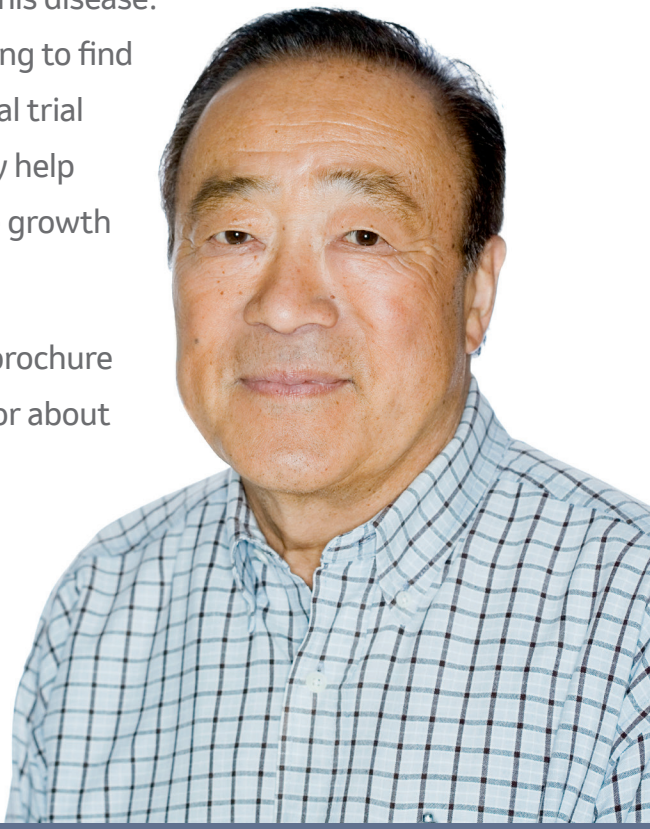


Table of Contents

- What is squamous non-small cell lung cancer (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 treatment being studied?
  - About V940
  - What are induction and maintenance treatments?
- 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 squamous NSCLC?

Non-small cell lung cancer (NSCLC) is a cancer that starts in your lungs and can spread to other parts of your body. It is the most common type of lung cancer. About 8 out of 10 lung cancers are NSCLC.

Squamous NSCLC is a less common type of NSCLC. Squamous NSCLC starts in the cells that line the airways and is usually found in the center of the lung next to airway (bronchus). 3 out of 10 people who are diagnosed with NSCLC have squamous NSCLC.

What are my treatment options?

If you have non-small cell lung cancer (NSCLC), 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
- Features of your cancer cells (called biomarkers) that may help guide your treatment

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.
- **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 non-small cell lung cancer (NSCLC), but it helps keep you as comfortable as possible.
- **Surgery** – treatment to remove all or part of the cancer
- **Clinical trials**, such as this one

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 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 drug, V940, when given with standard treatments for squamous NSCLC is safe and may help stop or slow down the growth of non-small cell lung cancer (NSCLC). Researchers will compare the investigational drug, V940 versus placebo when combined with pembrolizumab and platinum chemotherapy. A placebo looks like the study medicine but has no active ingredients. Using a placebo may help researchers better understand the real effects of the study medicine. V940 is experimental. It has not been approved to treat any type of cancer.

What treatment is being studied?

The trial is studying an investigational combination of study drugs.

The study drugs being studied are:

- The investigational combination of V940 (also known as mRNA-4157), with pembrolizumab, both of which are types of **immunotherpay**, and chemotherapy
- **Placebo** with pembrolizumab, and chemotherapy

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.

About V940 (mRNA-4157)

V940 is an investigational cancer therapy that has not been approved.

1. Every cancer has different mutations (changes) in its genes. V940 is made specifically for each person based on these gene mutations - in other words, it is individualized for each person.
2. Before a person gets V940, researchers find the cancer mutations by looking at the 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 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 the cancer mutations.
4. These proteins may help the immune system recognize and attack cancer cells with these mutations.

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 study doctor.

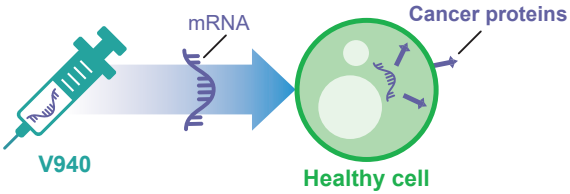
Another way to think about V940

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.

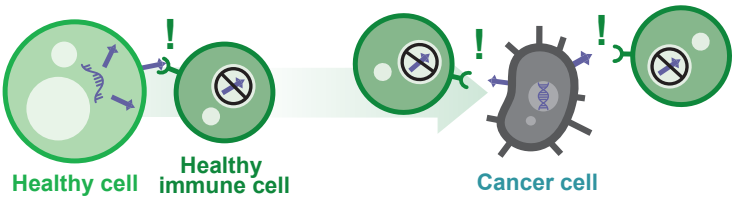
2

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**.



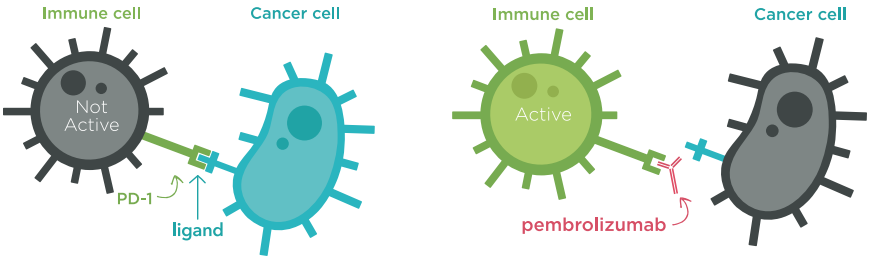
About pembrolizumab

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



What are induction and maintenance treatments?

This trial has two parts:

1. **Induction treatment:** In the first part of the study, you will receive treatment that includes chemotherapy.
2. **Maintenance treatment:** In the second part of the study, you will continue treatment after chemotherapy ends.

Both induction and maintenance treatments are meant to improve how well your main cancer treatment works.

The main cancer treatment for non-small cell lung cancer (NSCLC) is pembrolizumab plus chemotherapy induction treatment followed by pembrolizumab maintenance treatment.

In this trial, it is not known whether there is a benefit to adding the investigational drug, V940, to the induction and maintenance treatment setting.

Who can join this trial?

There are eligibility criteria that will determine if you will quality for participation.

For example, you must:

- Have stage IV squamous NSCLC
- Agree to provide tumor tissue which will be used to make mRNA to use in V940
- Be 18 years of age or older at the time of consent
- Have not had other treatment for stage IV NSCLC

There are other eligibility criteria in addition to the above. Your trial staff will do tests to see if you are able to join this trial.

You and your study 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 5 years

You should expect to be in the trial for up to 2 years of treatment and three years of follow-up

What will happen during trial visits?

You will visit the trial site on a regular schedule so that the study doctors can see how the study drugs are working for you.

During your trial visits, you may get:

- Biopsy
- Your assigned study drug treatment
- Physical exams
- Blood and urine (pee) tests
- Imaging scans, such as CT scans or MRIs (scans that help the study doctor see the cancer inside your body)

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

If you are able to join the study, your study 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?

Once your study doctor has confirmed you meet all the eligibility requirements, you will be randomly assigned to 1 of 2 groups. The investigational combination of study drugs you get depends on the group you are placed in, except for the first 6 weeks of treatment. For the first 6 weeks, all patients will receive pembrolizumab plus chemotherapy. After 6 weeks, a tumor assessment will be completed to make sure you can continue on with your group.

- **Group 1** will get the investigational combination of V940 (2 doses, given every 3 weeks) plus pembrolizumab (1 dose, given every 6 weeks) and chemotherapy (2 doses, given every 3 weeks) for 6 weeks

- **Group 2** will get placebo (2 doses, given every 3 weeks) plus pembrolizumab (1 dose, given every 6 weeks) and chemotherapy (2 doses, given every 3 weeks) for 6 weeks

Once you complete induction treatment, you will continue into the maintenance treatment part in your already assigned group:

- **Group 1** will get investigational combination of V940 (7 doses, given every 3 weeks) plus pembrolizumab (15 doses, given every 6 weeks) for up to 90 weeks
- **Group 2** will get placebo (7 doses, given every 3 weeks) plus pembrolizumab (15 doses, given every 6 weeks) for up to 90 weeks

A computer will decide which group you are put in. You have a 2 in 3 chance of being put in Group 1 and a 1 in 3 chance of being put in Group 2.

You, your study doctor, and the trial staff will not know what treatments you are getting. In case of a health emergency, they can find out.

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

You can use this brochure to talk with your doctor 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:

V940-013_PB_NA_English_V00.1_11JUL2025

Copyright © 2025 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.

For more information, contact our research staff: