KANDLELIT

ONCOLOGY CLINICAL TRIALS

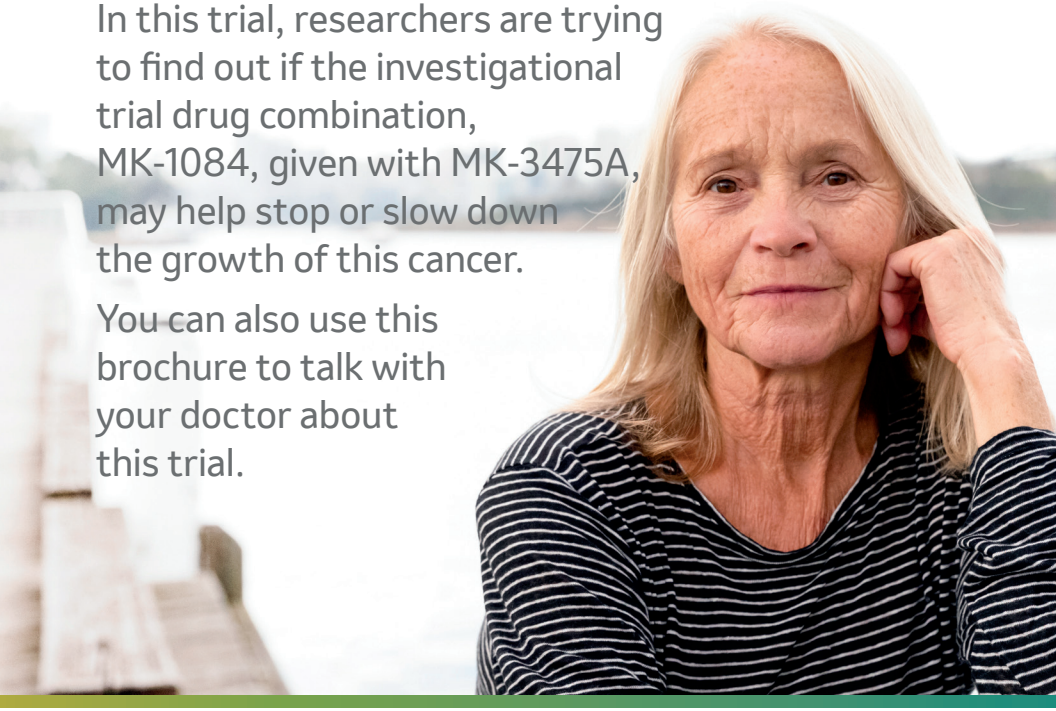
MK1084-007

Learn about a clinical trial for **non-small cell lung cancer (NSCLC) with KRAS G12C mutations**

In this brochure, you will learn about **non-small cell lung cancer (NSCLC) with KRAS G12C mutations** and a clinical trial for this disease.

In this trial, researchers are trying to find out if the investigational trial drug combination, MK-1084, given with MK-3475A, may help stop or slow down the growth of this cancer.

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



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What is non-small cell lung cancer (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.

What is KRAS G12C?

KRAS G12C is a gene mutation. Gene mutations are changes in your cells that affect how they work. Some mutations can cause cells to become cancerous and grow out of control.

KRAS G12C is a mutation of the KRAS protein, which is involved in cell growth. It keeps the protein in an “on” state which causes cells to grow too much. This can form tumors or help tumors to grow.

KRAS G12C mutation happens in about 5% to 15% of people (5 to 15 out of 100) who have NSCLC.

What are my treatment options?

If you have 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 1 or more of these treatments:

- **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 NSCLC, but it helps keep you as comfortable as possible.
- **Surgery** – treatment to remove all or part of the cancer
- **Watchful waiting** – your care team might wait and watch the cancer before they use any treatment (also called active surveillance)
- **Clinical trials**, such as this one

Talk to your doctor to find out which treatment is right for you.

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 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 an investigational trial drug combination, MK-1084 given with MK3475A, is safe and may help slow down the growth of NSCLC with KRAS G12C mutation.

MK-3475A is an injection (shot) given under the skin. It is made up of 2 trial drugs: pembrolizumab (pembro) and MK5180, which helps the body absorb and distribute drugs like pembro.

Getting pembro by injection (MK-3475A) is experimental. MK-3475A has not been approved to treat NSCLC. IV Pembro is an immunotherapy, which is a medicine that helps your immune system fight the cancer. Pembro has been approved for some types of NSCLC when given by a needle in a vein (IV Infusion) rather than as a shot. IV pembro may not be approved in your country for your exact type of NSCLC.

Researchers will compare these 2 investigational study treatments:

- The investigational combination of MK-1084 with MK3475A
- The investigational combination of MK3475A with chemotherapy

What treatment is being studied?

The investigational drug is MK-1084. Researchers are studying the investigational combination of MK-1084 and MK3475A.

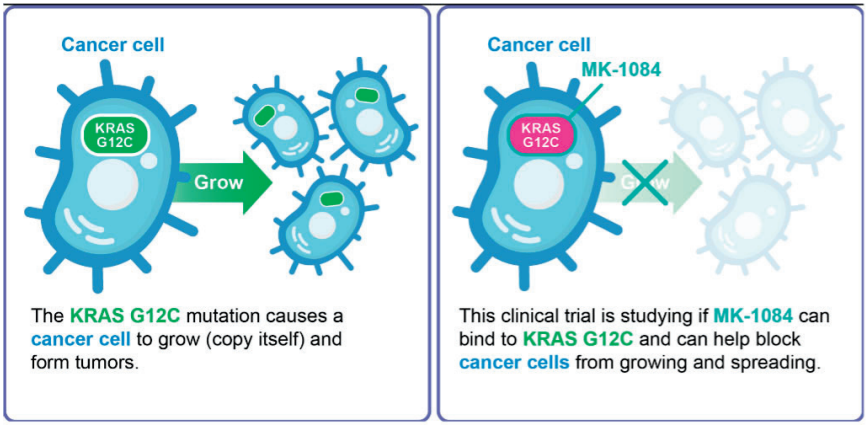
About MK-1084

MK-1084 is an investigational study drug. This clinical trial is studying if MK-1084 can bind to KRAS G12C and can help block cancer cells from growing and spreading.

Understanding MK-1084:

1. The KRAS protein in cells, including lung cells, turns on and off to help control cell growth.
2. In some cancer cells, a KRAS mutation (change) called KRAS G12C keeps the protein "on." This causes cancer cells to grow and tumors to form.
3. This is where MK-1084 comes in – researchers are studying if MK-1084 can bind with KRAS G12C and help block it.
4. By blocking the KRAS G12C mutation, MK-1084 may stop or slow down the growth of NSCLC.

Another way to think about MK-1084



About the trial medication?

Pembrolizumab (also called MK-3475) is a type of immunotherapy, which may help the body's immune system attack cancer cells.

Pembrolizumab as an IV infusion

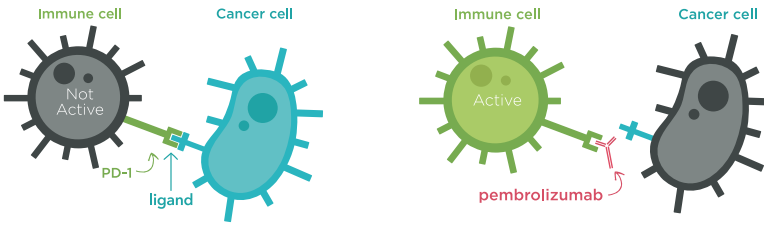
Pembrolizumab is usually given as an IV infusion, which is when a thin tube is inserted into a vein where it will stay long enough to allow the medicine to go into your body. Pembrolizumab as an IV infusion is already approved for treating various cancers, including certain patients with melanoma, ccRCC, or NSCLC. It may not be approved for some or all of these uses in your country.

Pembrolizumab as a SC injection

MK-3475A is an experimental form of pembrolizumab. It is a combination of pembrolizumab and another experimental drug called MK-5180, and is given as a SC injection (shot under the skin). When given as a shot under the skin, pembrolizumab is mixed with MK-5180 (also called hyaluronidase) to help the body absorb and distribute pembrolizumab to the cells.

How pembrolizumab works:

1. A protein on some of your immune system cells called PD-1 can bind with certain molecules called PD-L1. PD-L1 is found on some cancer cells.
2. When PD-1 and PD-L1 bind, it turns off your immune system cell. This means it can't do its work to help protect you and attack cancer cells.
3. Pembrolizumab works by binding with PD-1. This stops it from binding with PD-L1.
4. By stopping PD-1 from binding with PD-L1, pembrolizumab helps the immune system cell stay on. This way it can find and attack cancer cells.



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

For example, you must:

- Have been newly diagnosed with stage IIIB, IIIC not eligible for curative resection or chemoradiation, or stage IV NSCLC
- Have the KRAS G12C mutation
- Not have had or are not currently getting treatment for NSCLC

These are not the only requirements to join. 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 investigational study treatments

You may be in the trial for up to 6 years.

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 investigational study drugs are working for you.

During your trial visits, you may get:

- Biopsy
- Eye Exam
- Your assigned investigational study drug treatment
- Physical exams
- Blood and urine (pee) tests

- Electrocardiograms (ECGs)
- Imaging scans, such as CT scans or MRIs (scans that help the doctor see the cancer inside your body)

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 treatments will I get?

The investigational combination of study drugs you get depends on the group you are placed in.

If you meet all the trial requirements, you will be randomly assigned to 1 of 2 groups:

- **Group 1** will get the investigational combination of MK-1084 once a day, and MK3475A every 6 weeks, for up to 2 years
- **Group 2** will get the investigational combination of MK3475A every 6 weeks, and chemotherapy every 3 weeks for up to 2 years

A computer will decide which group you are put in. You have an equal chance of getting put in each group

You, your trial doctor, and the trial staff will know what treatments you are getting.

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

If you are eligible and join the trial, the trial 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 trial 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 trial 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 trial 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 trial, 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 trial doctor and tell them you do not want to be in the trial anymore.
2. The trial doctor will contact the trial 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 non-small cell lung cancer (NSCLC) with KRAS G12C mutations and this clinical trial

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

Notes: _____

To learn more

To learn more about this trial, you can:

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

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