20235844
#42829440.0

IRB Approved at the Protocol Level Feb 22, 2025

TroFuse 007

ONCOLOGY CLINICAL TRIALS

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

In this brochure, you will learn about (NSCLC) and a clinical trial for this disease. This clinical trial is trying to find out if an investigational study drug combination can help stop or slow down the growth of NSCLC.

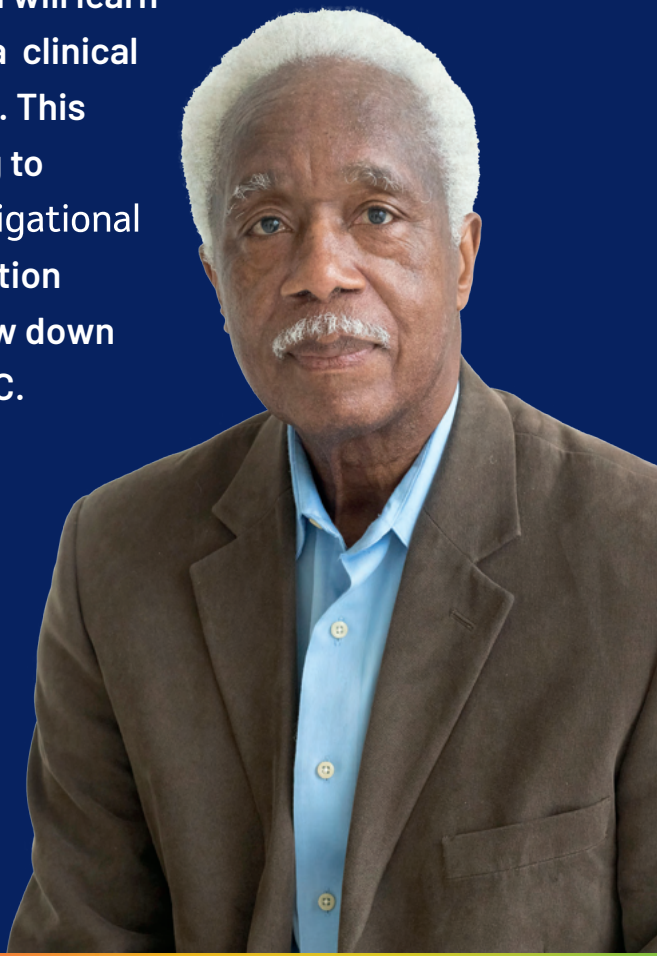


Table of Contents

What is Non-Small Cell Lung Cancer?

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 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.

Deciding to join a clinical trial is something only you, those close to you, and your doctors and nurses can do together.

About this clinical trial

Why is this trial being done?

This trial is trying to find out how well the investigational study drug sac-TMT plus pembrolizumab may work to help stop or slow down your NSCLC, compared to pembrolizumab alone. Researchers will also see what side effects may occur.

Who can join this trial?

You may be able to join this clinical trial if you have been newly diagnosed with metastatic NSCLC (NSCLC that has spread outside of the lungs) and being untreated for this disease.

Your trial team will give you certain tests, which will include testing a sample of your tumor for the protein PD-L1.

You and your trial doctor will discuss if this trial is a good option for you, as well as the possible benefits and risks of joining this trial.

What trial drug is being studied?

The investigational trial drugs being studied are called sac-TMT and pembrolizumab. sac-TMT is a type of chemotherapy drug. Pembrolizumab is a type of immunotherapy, which may help the body's immune system attack cancer cells.

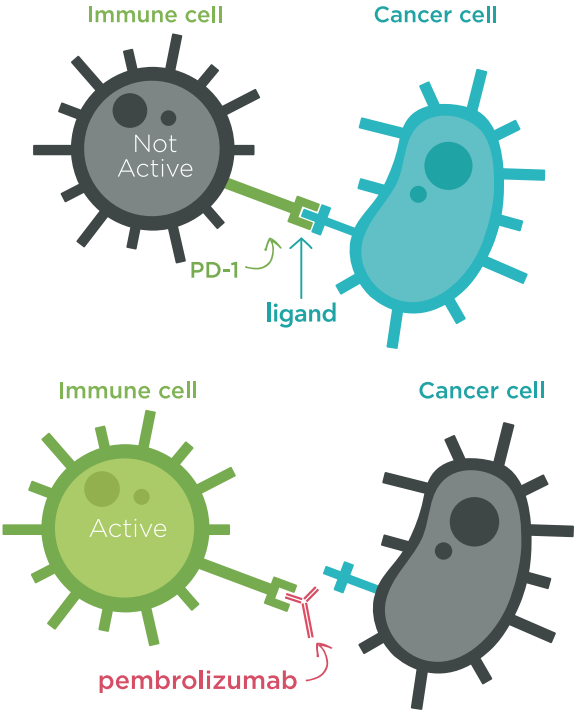
The information below is what researchers know or assume about how each study drug works on its own.

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 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.



About sac-TMT

sac-TMT is an investigational trial drug that is a type of targeted therapy known as antibody drug conjugate (ADC) that may destroy cancer cells. Unlike traditional chemotherapy, ADCs have 3 parts:

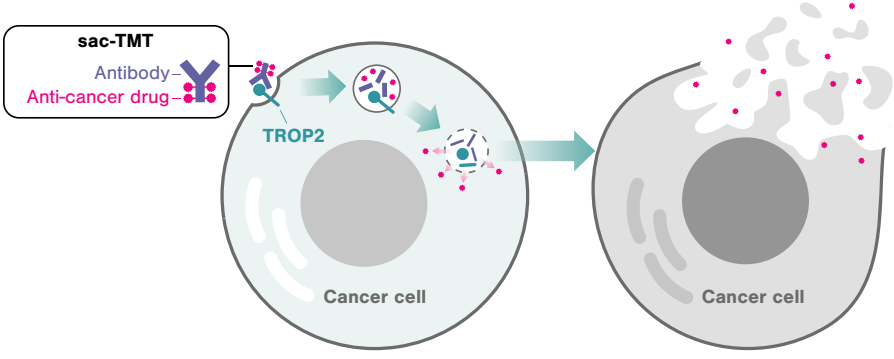
- **A monoclonal antibody:** A protein that binds to specific proteins or receptors found on certain types of cells, including cancer cells. In this case, the specific receptor is TROP2.
- **An anti-cancer drug:** A type of drug that is meant to kill cancer cells.
- **Linker:** Connects the anti-cancer drug to the monoclonal antibody.

How sac-TMT works

1. TROP2 receptors are involved in how tissues in the body grow. These are more common in cancer cells.
2. The monoclonal antibody in sac-TMT (investigational trial drug) finds and binds to the TROP2 receptors on cancer cells.
3. TROP2 moves sac-TMT into the cancer cell where the anti-cancer drug is released.
4. Once inside the cancer cell, the anti-cancer drug may kill the cancer cell.

This is what scientists know or assume about how the trial drug works.

Another way to think about sac-TMT



sac-TMT may kill the cancer cell.

The information above is what is known or assumed about how each study drug works on its own.

If I am able to join, what will happen during study visits?

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

During your trial visits, you might get:

- Blood tests
- Physical exams
- Research trial drugs
- Imaging scans such as CAT scans or MRIs

What drug will I get?

The drug you get depends on which group you are placed in. You will have an equal chance of being assigned to one of two groups:

- **Group 1** will get **sac-TMT** plus **pembrolizumab**.
- **Group 2** will get **pembrolizumab** alone.

If you join the trial your 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 trial drug works over time.

Ask your doctor any questions about what happens in the study visits and how often they will happen.

If I decide not to join this clinical trial, what are my other treatment options?

If you have metastatic NSCLC, your cancer care team will discuss your treatment options with you and those close to you. Your options will depend on several things:

- 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
- Side effects you might have from the treatment
- What chance the treatment has of reducing or removing the disease
- How long the treatment might help extend your life
- How much the treatment might help reduce your symptoms

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

- **Clinical trials**, such as this one
- Approved drugs or treatment, which are not investigational study drugs
- **Comfort care**, also called palliative care. This type of care does not treat your cancer directly but instead tries to help you feel better and keep you as active and comfortable as possible

Thank you for reviewing this information about NSCLC, and this clinical trial.

Your questions and notes:

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Contact Merck by
  - ➤ Visiting **www.merckoncologyclinicaltrials.com**
  - ➤ Scanning this QR code:

MERCK

TroFuse-007_PB_NA_English_V04.1