



A Clinical Trial for Advanced Esophageal Cancer

In this brochure, you will learn about **esophageal cancer (cancer of the esophagus)** and a clinical trial for this disease. This clinical trial is trying to find out if chemotherapy combined with an investigational immunotherapy and targeted therapy, can help stop or slow down the growth of advanced esophageal cancer.

What is Esophageal Cancer?

Esophageal cancer is a cancer that starts in your esophagus. Your esophagus is the tube that carries food and fluid from your mouth to your stomach. Esophageal cancer can spread to other parts of your body.

There are 2 common types of esophageal cancer:

- 1) Esophageal adenocarcinoma – often starts in the lower part of your esophagus.
- 2) Esophageal squamous cell carcinoma (ESCC) – often starts at the top and middle of your esophagus.

For this trial, you must have only esophageal squamous cell carcinoma to be eligible.

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 study investigational treatments and procedures.

This clinical trial may include people with cancer that has:

- Just been diagnosed
- A high chance of coming back after it has been removed
- Spread while on other cancer treatments

Your treatment options

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

- 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 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:

Surgery – removes all or part of the cancer

Watchful waiting – your care team might wait and watch your disease before they use any treatment (also called active surveillance)

Chemotherapy – use of medicine (drugs) to kill cancer cells

Pembrolizumab plus chemotherapy – treatment that helps the body's immune system attack cancer cells.

Radiation therapy – use of high energy radiation to kill cancer cells and shrink tumors

Clinical trials, such as this one



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



All about this clinical trial

Why is this study being done?

This study is trying to find out if the combination of two research study drugs, and chemotherapy, work to help stop or slow down the growth of advanced esophageal cancer. The study is also trying to find out what side effects patients have when they take the two study drugs together. Researchers don't know if these study drugs work together to treat this type of cancer.

The treatments being studied

One drug being studied is called pembrolizumab (also known as MK-3475). The other drug being studied is called lenvatinib.

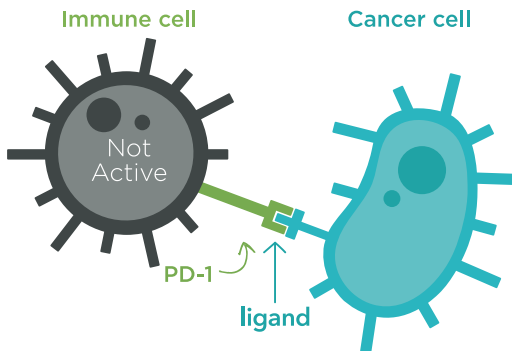
What is pembrolizumab?

Pembrolizumab is a type of immunotherapy, which may help the body's immune system attack cancer cells.

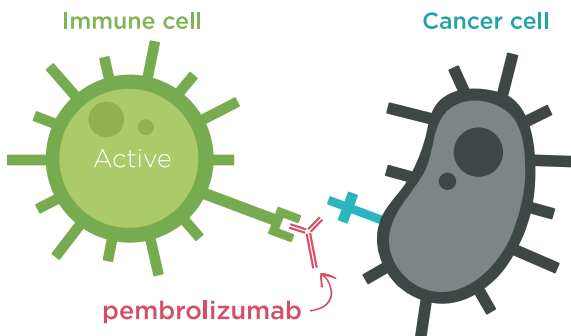
About pembrolizumab:

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 2 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 the treatment



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.

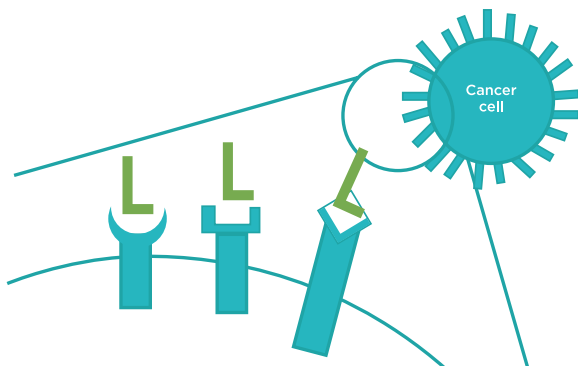


What is lenvatinib?

Lenvatinib is a type of targeted therapy known as a receptor tyrosine kinase inhibitor (RTKI) that may help cut off the blood supply that feeds the cancer, and may slow the rate at which cancer cells grow.

About lenvatinib:

1. Proteins called receptor tyrosine kinases (RTKs) are involved in the development of new blood vessels that supply oxygen and nutrients to cells and help them grow.
2. These proteins can be present in high amounts in cancer cells.
3. By blocking the action of these proteins, lenvatinib may slow the rate at which the cancer cells grow and may help cut off the blood supply that feeds the cancer.



The combination of pembrolizumab and lenvatinib is investigational. The information above is what is known or assumed about how each study drug works on its own.

This clinical trial is studying how well the combination of the research study drugs (lenvatinib and pembrolizumab in combination with chemotherapy) may work to help stop or slow down your esophageal cancer compared to pembrolizumab plus chemotherapy.



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

Who can join this study?

There are certain criteria that you must meet in order to join. Your study team will give you certain tests, which will include testing a sample of your tumor for the protein PD-L1.

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

If I join, what will happen during study visits?

You will visit the study site on a regular schedule so that your doctors can see how the study drug is working for you. During your study visits, you might get:

- Blood tests
- Physical exams
- Research study drugs
- Imaging scans such as CT scans or MRIs

What drugs will I get?

The drug you get will depend on which part of the trial you enter and which group you are placed in.

About 862 people will participate in the trial. This trial has 2 groups. You have an equal chance of being in each group. The group you are in will be decided by a computer.

Group 1: Pembro + lenvatinib + chemo (FP, TP, or mFOLFOX 6)* followed by pembro + lenvatinib

Group 2: Pembro + Chemo (FP, TP, or mFOLFOX6)*

*TP chemo regimen may only be administered to participants in China, Hong Kong, Republic of Korea, and Taiwan

If you join the study, your doctor will need to stay in contact with you even after your study visits are over.

This is very important because this clinical trial is studying how well the study drugs work over time.

To learn more

Talk to your study doctor or contact:



www.merckoncologyclinicaltrials.com



Clinical Trials 101 video
www.merckoncologyclinicaltrials.com



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