

KANDLELIT

ONCOLOGY CLINICAL TRIALS

MK-1084-012

Learn about a clinical trial for **advanced colorectal cancer with KRAS G12C mutation**

In this brochure, you will learn about advanced **colorectal cancer with KRAS G12C mutation** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational study drug, called MK-1084, taken in combination with other treatments is safe and may help slow or stop the growth of advanced colorectal cancer with KRAS G12C mutation in people who have not yet had treatment.

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



Table of Contents

- What is advanced colorectal cancer?
 - What is KRAS G12C?
 - 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 MK-1084
- 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 treatment will I get?
- Notes

What is advanced colorectal cancer?

Colon cancer is a type of tumor that starts in the large intestine, or colon. Rectal cancer starts in the rectum, which is the last few inches of the colon. Together, these are known as colorectal cancer. Colorectal cancer is the third most common cancer in the world. While the exact cause of colorectal cancer is unknown, almost 90% of cases occur in people 50 years of age or older.

Advanced colorectal cancer is when the cancer has begun to spread outside of where it started. Advanced cancers can be locally advanced unresectable or metastatic.

- **Locally advanced** means that cancer has grown to nearby tissue or lymph nodes but has not yet spread to other parts of your body. **Unresectable** means the cancer can't be fully removed with surgery.
- **Metastatic** means the cancer has spread from where it started to other parts of your body.

What is KRAS G12C?

Doctors often test people with colorectal cancer for gene mutations. Gene mutations are changes on your DNA (genes) that affect how cells in your body work.

KRAS G12C is a mutation of KRAS gene. The KRAS gene sends signals that tell cells when to grow. The G12C mutation causes the KRAS gene to send too many signals, and cells to grow out of control. This causes cancer.

KRAS G12C mutation happens in about 3% (3 out of 100) of people who have locally advanced unresectable or metastatic colorectal cancer.

What are my treatment options?

If you have locally advanced unresectable or metastatic colorectal cancer, 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
- 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



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.

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 locally advanced unresectable or metastatic colorectal cancer, 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.

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 study drug called MK-1084 taken in combination with other treatments is safe and may help slow down or stop the growth of locally advanced unresectable or metastatic colorectal cancer with KRAS G12C mutation.

MK-1084 will be taken in combination with:

- **Cetuximab** - a targeted therapy, which targets specific features of cancer cells
- **mFOLFOX6** - a chemotherapy, which works to destroy cancer cells or may stop them from growing

Researchers will compare MK-1084 with cetuximab and mFOLFOX6 to mFOLFOX6 taken with or without bevacizumab (another targeted therapy). mFOLFOX6 with or without bevacizumab are treatments people usually get for this cancer with KRAS G12C mutation.

What treatment is being studied?

The investigational study drug is MK-1084. In this clinical trial, researchers are studying MK-1084 taken in combination with cetuximab and mFOLFOX6.

MK-1084 is experimental. It is not approved when given alone or in combination with any other treatments.

About MK-1084

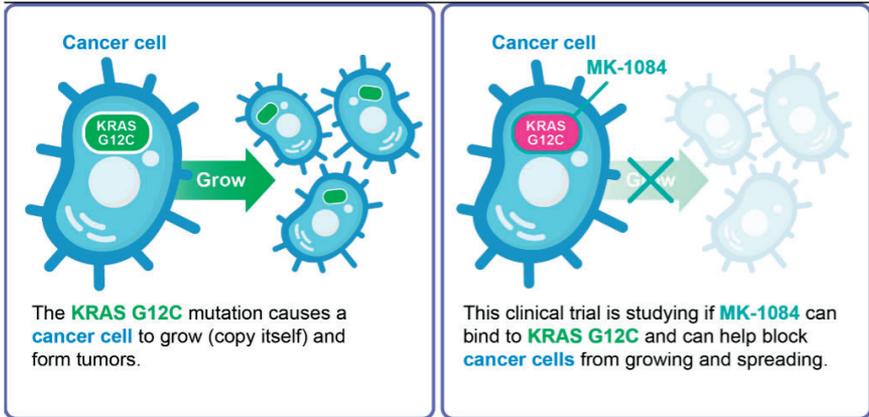
MK-1084 is an investigational study medicine. This clinical trial is studying if MK-1084 can bind to KRAS G12C and can help block cancer cells from growing and spreading.

MK-1084:

1. The KRAS protein in cells, including colorectal 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 colorectal cancer.



Another way to think about MK-1084



Who can join this trial?

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

For example, you must:

- Have been diagnosed with locally advanced unresectable or metastatic colorectal cancer.
- Have the KRAS G12C mutation

Your trial staff will do certain tests to see if you are able to join this trial. This will include testing a sample of your tumor for the KRAS G12C mutation.

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
- How well you tolerate the study treatments

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 trial drugs are working for you.

During your trial visits, you may get:

- Your trial treatments
- Blood and urine (pee) tests
- Physical exams
- Eye exams
- Checks of your vital signs, such as blood pressure
- Questionnaires about how you are feeling
- Tests of your heart function, including an electrocardiogram (ECG)
- 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 overtime.

What treatments will I get?

There are two parts to this trial. The trial drugs you get will depend on when you join the trial and which part is open. The trial doctor and staff can tell you whether you are joining the trial during the first part or second part.

If you join during the first part of the trial, you will receive the investigational drug, MK-1084, in combination with cetuximab and mFOLFOX6.

After the first part is completed, the second part will start.



The second part of this trial has 2 groups:

- **Group 1** will get the investigational drug MK-1084, in combination with cetuximab and mFOLFOX6
- **Group 2** will get mFOLFOX6, with or without bevacizumab

In the second part of this trial, a computer will decide which group you are placed in. You have an equal chance of being placed in either group.

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

People will take MK-1084 as a tablet by mouth once daily. People will get cetuximab, mFOLFOX6, and bevacizumab through a vein as an intravenous (IV) infusion once every 2 weeks.

Thank you for learning about advanced colorectal cancer with KRAS G12C mutation 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:

