

Frequently asked Questions...

ABOUT E4203: A CLINICAL TRIAL FOR PATIENTS WITH METASTATIC OR RECURRENT COLORECTAL CANCER

The Eastern Cooperative Oncology Group (ECOG) prepared this fact sheet to help you understand this cancer clinical trial.

What is a clinical trial?

A clinical trial is a study conducted by doctors to test new medications or new combinations of medications. This trial – ECOG Trial E4203 – is what is called a “phase two” trial. That means that the new approach is being studied to determine effectiveness against your type of cancer, as well as for safety of the new treatment.

What is the purpose of this trial?

The purpose of the trial is to see if the amount of a specific protein in the tumor (thymidylate synthase or TS) can help physicians select the most appropriate therapy for patients with colon and rectal cancer that has spread to other areas of the body. The level of TS will be measured in a tumor biopsy. This information will help select the type of treatment that you will receive.

If you have already had a biopsy of your colon cancer to confirm a recurrence or a spread of the cancer to other organs, you may not need an additional biopsy in order to take part in this study.

What should I know about the trial treatments?

Your tumor will be analyzed and results returned to your doctor within three business days. If the level of TS is low, standard therapy will be given. Standard therapy is 5-FU combined with other chemotherapy drugs (oxaliplatin and bevacizumab). Because 5-FU may not be as effective in people whose tumors have a high TS level, some of these patients will receive a treatment regimen that has another drug instead of 5-FU (irinotecan, oxaliplatin, and bevacizumab). This particular combination of chemotherapy drugs is considered experimental although each of the three drugs individually is FDA approved.

What are some of the side effects caused by these medications?

Chemotherapy drugs in general cause side effects including loss of appetite, diarrhea, constipation, nausea, vomiting, and risk of infection. There are medications available that can help control the severity of side effects. Some people tolerate side effects better than others. More information on side effects can be found on the National Cancer Institute Web site at <http://www.cancer.gov/cancertopics/chemotherapy-and-you/page4>.

What will I have to do on the clinical trial?

If you decide to participate in this trial, you can expect the following:

- Pregnancy test for female patients;
- Complete physical exam and physician visit at the beginning of each cycle of treatment;
- Blood samples, chest x-rays, CT scans or MRI;
- Electrocardiogram; and
- Tumor biopsy (if a previous biopsy is not available).

You would most likely need to have most of these tests anyway as part of your care for colorectal cancer. Your doctor or nurse will help you set up a schedule for your tests.

Will insurance cover the cost of this trial?

Medicare covers the routine costs of care required in clinical trials. Many other insurers also cover these costs. Coverage may not, however, be the same from plan to plan. You or your insurance company will not be charged for the tests required by this trial and performed by designated laboratories. Please discuss these issues with your healthcare provider and your insurer.

Is this trial right for me?

To be accepted into this trial, you must have metastatic colorectal cancer. If you have not yet been treated with chemotherapy for your cancer, you may be eligible for this trial. Men and women of all ages and ethnic groups can participate.

If you would like to know more about this trial, talk to your doctor. He or she can tell you whether this trial is right for you. If you decide to participate, your doctor will help you enroll.



What if I change my mind after enrolling in the trial?

You may stop treatment at any time – please discuss your concerns with your doctor.

Would my doctor stop my participation for any reason?

Your doctor will carefully observe your health throughout the trial. Your doctor may stop your participation if:

- Your disease progresses;
- You have serious side effects;
- New information on treating metastatic colorectal cancer becomes available that may affect your health or welfare.

Who is conducting the trial?

The Eastern Cooperative Oncology Group (ECOG) is conducting this trial. ECOG is one of the largest cancer research organizations in the United States. It has a network of researchers, physicians, and healthcare professionals at public and private institutions across the country. ECOG conducts clinical trials in all types of adult cancers. It receives funding from the National Cancer Institute (NCI) and other sources. ECOG's goal is to control, effectively treat, and ultimately cure cancer. ECOG provides research results to individuals and the medical community through scientific publications and professional meetings.

Where can I get more information?

For more information about ECOG, visit www.ecog.org.

For more information about cancer and clinical trials, visit:

The Coalition of Cancer Cooperative Groups: www.CancerTrialsHelp.org

The National Cancer Institute (NCI) Cancer Information Service:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615,

http://cancer.gov/clinical_trials for clinical trial information and

http://cancer.gov/cancer_information for more information about cancer.

