

Frequently asked Questions...

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

ABOUT E5204: A CLINICAL TRIAL FOR PEOPLE WITH STAGE II OR III RECTAL CANCER

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 E5204 – is a phase III trial. That means that the new treatment has already been tested in different doses for safety and has been proven effective against **colon** cancer for patients who have had surgery to remove the cancer. ECOG is testing this chemotherapy treatment to see if it is effective for patients who have had surgery to remove **rectal** cancer.

What is the purpose of this trial?

This trial is evaluating the positive and negative effects of a standard chemotherapy treatment with and without a new medication called bevacizumab (trade name: Avastin) in patients with rectal cancer that has been surgically removed.

What are the drugs being used in this trial?

The chemotherapy drugs used in this trial are FDA-approved. They are 5-fluorouracil (often called 5-FU), leucovorin, and oxaliplatin. Bevacizumab is considered experimental for this type of cancer, but it has been approved to treat other cancers.

What should I know about the trial treatments?

If you choose to participate in this study, you will be randomized to one of two treatments. Randomization means that patients are assigned to a group by chance; you will have an equal chance of assignment to a group. Neither you nor your doctor will know which treatment you receive. This is to be sure the effects of the treatment are evaluated objectively.

One group will receive the standard treatment of 5-FU, leucovorin, and oxaliplatin. The second group will receive the same standard treatment plus bevacizumab.

First Group (Arm A) Receives:	Second Group (Arm B) Receives:
Oxaliplatin	Oxaliplatin
Leucovorin	Leucovorin
5-FU	5-FU
	Bevacizumab

All of the drugs in this trial are given through an injection in a vein.

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

The side effects most frequently experienced include nausea, vomiting or diarrhea, increased risk of infection, bruising, or bleeding, fatigue, muscle weakness, and fever. Rare side effects include seizures, blood clots and intestinal damage. Your doctor will discuss all the side effects of bevacizumab and standard treatment with you.

What will I have to do on the clinical trial?

If you decide to participate in this trial, your doctor may perform several tests before and during your treatment. These include:

- Pregnancy test for female patients;
- Complete physical exam;
- Blood tests;
- Chest x-rays, CT scans or MRI.

Most likely, you would receive these tests as part of your routine care for rectal cancer. These tests will be repeated occasionally during the trial. Your doctor or nurse will help you set up a schedule for your tests.

You will also be asked to complete brief questionnaires about your bowel function.

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. Oxaliplatin and bevacizumab, the investigational drug, will be provided at no cost to you. The cost of 5-FU, leucovorin, doctor's visits, and certain tests may or may not be covered by your insurer. 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 rectal cancer that has been treated with chemotherapy, radiation, and surgery. Men and women of all ethnic groups can participate.

If you would like to participate in this trial, let your doctor know. Your doctor can discuss with you whether this trial is right for you. If you decide to participate, your doctor will help you understand all the details of the study through a process called "informed consent" before you enroll.

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

You may leave the trial 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 status throughout the trial. Your doctor may stop your participation if:

- Your disease progresses;
- You have serious side effects;
- New information on treating rectal 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.

National Cancer Institute's Guide "Clinical Trials and Insurance Coverage – A Resource Guide"

www.nci.nih.gov/ClinicalTrials/Insurance

