

PATIENT GUIDE to the **CLEAR COLON TRIAL**

Celecoxib and Length of Adjuvant Rx

CALGB 80702/SWOG 80702

Learning you have cancer can be overwhelming for both you and your family. You may have heard about treatment options, and may be uncertain about your cancer therapy. This guide can help you understand one option – the CLEAR Colon Trial – to consider after colon cancer surgery. You should discuss this with your cancer doctor or surgeon to see if it is an option for you.

What is the CLEAR Colon Trial?

The CLEAR Colon Trial is a phase III study, conducted by the Cancer and Leukemia Group B (CALGB) and supported by the National Cancer Institute (NCI), that compares different treatments for colon cancer to each other. It will help decide if adding a new drug to standard chemotherapy (anti-cancer drugs) is more effective than standard chemotherapy alone, and if a shorter amount of time (or duration) of chemotherapy is as effective as the standard duration. This can only be known by doing a clinical trial.

Patients may be eligible for the CLEAR Colon Trial if they have had surgery for colon cancer. They also must have stage III colon cancer, meaning that the cancer has not spread to other parts of the body, but the lymph nodes that were removed with part of the colon contained some cancer. Some patients with stage III colon cancer will not have any more cancer problems, while other patients may have their cancer return (also called recurrence). Past clinical trials have shown that chemotherapy may lower the chance of recurrence. Currently, most patients with stage III colon cancer get about six months of chemotherapy with three drugs: 5-fluorouracil (5FU), leucovorin and oxaliplatin. This combination of drugs is known as FOLFOX.

Why is this Study Being Done?

To help better treat patients with colon cancer, the CLEAR Colon Trial wants to answer these questions:

- Does adding celecoxib (an oral drug like aspirin or ibuprofen, but not the same) to standard chemotherapy improve survival in certain patients with colon cancer after surgery?
- Is three months of chemotherapy as effective in preventing or delaying colon cancer recurrence as the standard six months of chemotherapy?

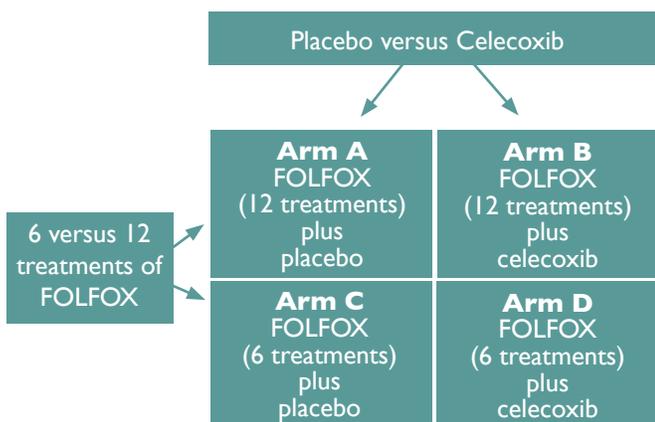
The drug celecoxib is being evaluated to determine if adding it to standard chemotherapy can further reduce the risk of cancer coming back. It is a nonsteroidal anti-inflammatory drug that is in the same class as aspirin, ibuprofen and naproxen. It is a pill and taken by mouth. Studies have shown that celecoxib and other drugs like it can reduce the chance of getting polyps (abnormal growths in colon that may turn into cancer) and reduce the risk of getting colon cancer in patients with prior polyps. It is not known if celecoxib can reduce the risk of cancer coming back in patients already diagnosed with colon cancer. One-half of the patients will get celecoxib and the other half will get placebo (pills with no medicine). They will be given either celecoxib or placebo starting within the first two weeks of chemotherapy and continuing for three years.

In addition, the duration of chemotherapy after surgery is being evaluated. In this study, we hope to learn if six months of chemotherapy is necessary to keep cancer from coming back or if less chemotherapy is as effective in preventing cancer recurrence. This might reduce the risk and/or severity of certain side effects. This aspect of the trial is part of an international effort in which patients from other countries (mainly in Europe) are enrolling in similar trials. Data from these trials will be used to get the most accurate answer to whether less chemotherapy can be given to future stage III colon cancer patients.

What is the Treatment Plan?

In the CLEAR Colon Trial, there are four treatment groups also called arms (see picture below). Patients will be put into these groups by chance (also called randomization) to make sure that the patients and tumors in each group are comparable. Neither the patient nor doctor can pick which treatment the patient gets. A computer will select the patient's treatment group (or arm), when the patient agrees to join the trial. In the treatment groups, patients will get the chemotherapy treatment, FOLFOX, for six treatments (about three months) or 12 treatments (about six months). Patients will also be given a study medication that will contain either celecoxib or placebo. Neither the patient nor doctor will be told which study medication the patient will get. The placebo will look just like celecoxib. In case of an emergency, the doctor may be able to find out whether the patient is getting the celecoxib or the placebo. If this happens, the patient will be removed from the study.

Study Schema



Are There Any Risks?

There are risks to taking part in any research study. More than 20 years ago, it was standard to give 12 months of chemotherapy after colon cancer surgery, and then there were trials conducted that demonstrated six months of chemotherapy was as effective. In this trial, some patients will receive six treatments of FOLFOX (about three months) instead of the standard 12 treatments (about six months), which may or may not be less effective in preventing cancer recurrences and improve survival. In addition, some patients will be given celecoxib that may or may not prevent cancer recurrences or improve survival and may add additional side effects. Before agreeing to this (or any clinical trial), you should discuss with

your doctor the risks of the study and whether these risks are reasonable for your particular situation. Prior to going on a trial, you will be given an informed consent form. Before participating in any study activities, all clinical trial participants are required to sign the informed consent form which indicates that you have read the form (or have had it read to you), and that you understand the information, have had your questions answered, and that you agree to take part in the study. The informed consent form includes detailed information about the study including risks and discomforts. This form also confirms that you are free to withdraw from the study at any time. Before signing, you should read the form carefully and discuss any questions with your doctor.

Taking part in this study may or may not make your health better. While doctors hope that adding celecoxib to FOLFOX may decrease the risk of cancer recurrence compared to FOLFOX alone, there is no proof of this yet. Furthermore, while doctors hope that the shorter course of FOLFOX (six treatments) will be as effective as a longer course of FOLFOX (12 treatments), there is no proof of this yet.

Does It Cost Anything to Participate?

You or your insurance company will be charged for portions of your care that are considered standard care. The cost of 5-fluorouracil (5FU), leucovorin and oxaliplatin (known as FOLFOX) will be charged to you or your insurance company. You may be responsible for co-payments and deductibles that are typical for your insurance coverage. Celecoxib/placebo will be provided at no charge while you take part in this trial. You will not be paid for taking part in this trial.

The NCI provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found on the NCI Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>

For More Information

To learn more about the CLEAR Colon Trial (CALGB 80702/SWOG 80702), contact your health care provider.

The Cancer and Leukemia Group B (CALGB) and the Southwest Oncology Group (SWOG) are among the nation's largest National Cancer Institute-supported cancer clinical trials cooperative groups. They work to improve the practice of medicine in preventing, detecting and treating cancer.