The COBRA Study: Using cancer DNA in the blood to predict if chemotherapy will benefit patients who have had surgery for early stage colon cancer

NRG Oncology Clinical Trial: NRG-GI005

Phase II/III Study of Circulating tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)

About the Trial

This study is being done to answer the following question:

Can we determine whether to recommend chemotherapy or no further treatment after surgery for an early stage colon cancer, by taking a blood sample and testing for the presence of circulating tumor DNA (ctDNA)?

We are doing this study because we want to find out if testing for ctDNA and offering additional chemotherapy for those who test "positive" is better or worse than the usual approach for early stage colon cancer that has been treated with surgery only. We are also doing this study to see if the ctDNA test can identify patients with colon cancer after surgery who do benefit, and also those who do not benefit, from receiving chemotherapy. The usual approach in this situation for most people with early-stage colon cancer is surgery alone.

ClinicalTrials.gov Identifier:
NCT04068103

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About NRG Oncology

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types.

NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI.

To contact NRG Oncology,
Call 267-519-6630 or
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Frequently Asked Questions

What is a clinical trial?

Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?

Men or women who have early stage (stage IIA) colon cancer that has been treated with surgery and for whom chemotherapy would otherwise not be recommended by the treating doctor.

Am I required to be in this study?

No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time.

What are the possible study treatments?

This study has 2 groups. If you are in the first group, your care is as it would be if you were not in the study. You will receive regular check-ups with your doctor after you join the study, but no further treatments for your colon cancer are necessary. You will have blood collected at different time points when you would be in the doctor's office anyway, and it would be stored and tested in the future for ctDNA.

If you are in the other group in which your blood is tested at the beginning of the study, your treatment will be determined by whether or not ctDNA is found in your blood. If ctDNA is found in your blood, you will receive chemotherapy for about 6 months after joining the study. The treatment will be one of the usual chemotherapy regimens for colon cancer: 5-fluorouracil (5-FU), leucovorin, and oxaliplatin (mFOLFOX6); or capecitabine and oxaliplatin (CAPOX). Your doctor will decide which of these regimens you receive. If ctDNA is not detected in your blood, you will receive regular check-ups with your doctor after you join the study but without any further treatment after surgery for your colon cancer.

How long will I be in this study?

Patients will be followed for 3 years after joining the study.

Are there side effects?

Chemotherapy may cause side effects. Your doctor will review all of the possible side effects with you if chemotherapy is part of your treatment as part of this study. It is important to tell your doctor about any side effects during the study so that they may be addressed and so that potential adjustments may be made.

More Information

Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer. You may also call: 1-(800)-4-CANCER (1-800-422-6237)