Using cancer DNA in the blood (ctDNA) to determine management for patients who have had surgery for colon cancer

NRG ONCOLOGY

Advancing Research. Improving Lives.™

ABOUT THE TRIAL

NRG-GI008: Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-NORTH AMERICA)

About the trial

NRG-GI008 is a clinical trial designed to determine whether chemotherapy is needed and if so, what kind of chemotherapy to recommend to patients based on the presence or absence of circulating tumor DNA (ctDNA) after surgery for colon cancer.

We want to find out if ctDNA testing results can be used to determine if the usual chemotherapy approach (5-fluorouracil [5-FU], leucovorin, and oxaliplatin [FOLFOX], or capecitabine and oxaliplatin [CAPOX]) or mFOLFIRINOX (5-FU, leucovorin, oxaliplatin, and irinotecan) may be used to prevent colon cancer from returning in patients who are ctDNA positive and if the usual approach compared to ctDNA testing every 3 months in ctDNA negative patients may be used to prevent colon cancer from returning.

Alternatively, for those patients who are ctDNA negative, we want to find out if the usual chemotherapy approach (5-fluorouracil [5-FU], leucovorin, and oxaliplatin [FOLFOX], or capecitabine and oxaliplatin [CAPOX]) or just continued close monitoring with repeat ctDNA and CT scans every 3-6 months should be used.

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 email info@nrgoncology.org

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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?
You may be able to take part in this research study if you have colon cancer that has been treated with surgery but has spread to the lymph nodes. This is known as stage III colon cancer. Or, if you have stage IIB or IIC colon cancer that has been treated with surgery but has not spread to the lymph nodes, you also may be able to join this study. Your healthcare team is the best source for information about your treatment options.

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. If you decide not to take part in this study, your doctor will discuss other treatment options.

What are the possible treatments?
This study has four study groups, Group 1 and Group 2 are for patients who are ctDNA negative and Group 3 and Group 4 are for patients who are ctDNA positive.

Group 1 and Group 2 (for patients with a ctDNA negative test)
If you are in Group 1, you will get chemotherapy, FOLFOX (5-FU, leucovorin, and oxaliplatin) for 3-6 months or CAPOX (capecitabine and oxaliplatin) for 3 months, as decided by your study doctor.

If you are in Group 2, you will be monitored with ctDNA testing every 3 months for 3 years, and you will not be treated with chemotherapy unless your ctDNA testing turns positive. Patients who develop a positive ctDNA test during monitoring will be asked to change to the ctDNA positive group and be randomized to Group 3 or Group 4.

Group 3 and Group 4 (for patients with a ctDNA positive test, either at the time or enrollment or after they were in Group 2)
If you are in Group 3, you will get FOLFOX or CAPOX for 6 months, as decided by your study doctor. If you are in Group 4, you will get mFOLFIRINOX (5-FU, leucovorin, oxaliplatin, and irinotecan) for 6 months.

How long will I be in this study?
After you finish your treatment, your doctor and study team will watch you for side effects. They will check you every 6 months for four and a half years after treatment. If you are ctDNA negative and do not develop a positive ctDNA test, you will receive regular check-ups every 6 months for four and a half years after you join the study without further treatment for your colon cancer.

If you are ctDNA negative and develop a positive ctDNA test during monitoring and agree to change to the ctDNA positive group (Group 3 or Group 4) and receive study treatment, your doctor and study team will watch you for side effects, after you finish your treatment. They will check you every 6 months for four and a half years after treatment. It is possible that you could be on the study up to eight years.

Are there side effects?
Chemotherapy may cause side effects. There are also potential risks associated with ctDNA testing. Your doctor will review all of the possible side effects with you. 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).