The COMMIT Study: Comparing the Addition of the Drug Atezolizumab to the Usual Treatment Approach for Colorectal Cancer

NRG Oncology / SWOG Clinical Trial: NRG-GI004 / SWOG S1610

Colorectal Cancer Metastatic dMMR/MSI-H Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab/Atezolizumab Combination Versus Single Agent Atezolizumab in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR)/Microsatellite Instability High (MSI-H) Metastatic Colorectal Cancer

About the trial

NRG-GI004/SWOG-S1610 is a clinical trial that is studying two treatment options for patients with colorectal cancer that has spread to other parts of their body (metastatic). This study is specifically for patients who have a particular type of metastatic colorectal cancer called “MSI-high” or “DNA repair deficient” (these two terms are sometimes used to describe the same thing). This can be learned by doing a specific test on a small piece of the cancer that was used to diagnose the colorectal cancer. For patients with this type of colorectal cancer, doctors know that new medicines may help the patient’s own immune system attack the cancer and this treatment has become a standard. However, these immune system treatments do not work for every “MSI-high” or “DNA repair deficient” metastatic colorectal cancer patient and traditional chemotherapy remains needed for many. This study is trying to answer the question of whether adding traditional chemotherapy and biologic treatment to immunotherapy improves the efficacy compared to immunotherapy alone. Therefore, patients in this study will be randomly assigned to receive one of two treatment options: immunotherapy (using the drug atezolizumab) alone or the same immunotherapy in combination with the chemotherapy and biologic treatment - frequently used for this type of cancer at later lines of therapy - when immunotherapy doesn’t work.

If you agree to take part in this study, you will also have the opportunity to participate in optional sample collections for use of your blood and tumor samples in possible future research studies. An additional sample of tumor tissue from your previous biopsy or surgery and blood samples will be collected if you choose to participate in the sample collection. Researchers use these samples to help them learn more about your cancer, using blood and tissue to find new ways to prevent, detect, treat, or cure cancer.

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About NRG Oncology

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of people with cancer. 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 comprises multidisciplinary investigators, including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians, and encompasses 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

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 may be able to participate if they have colorectal cancer that is known to have a specific alteration that may or may not be hereditary (MSI-high/DNA mismatch repair deficient), has spread to other parts of their body (metastatic), and they have not yet received treatment for their metastatic colorectal cancer. Your healthcare team is the best source for information about your treatment options, including cancer clinical trials. Be sure to take this information to your doctor to discuss your questions and concerns in general and specific to this trial.

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 with you.

Why are we doing this study?

Patients whose tumors have the above molecular changes are sensitive to immunotherapy with drugs (anti-PD-1; anti-PD-L1) such as atezolizumab and these drugs alone may be as good as chemotherapy for the kind of patients being treated in this study. However, we believe that combining atezolizumab with chemotherapy and biologic therapy may be better than atezolizumab alone. This question has not been addressed in any other studies.

What are the possible treatments?

All patients will be randomly assigned to one of two groups in the study. Group 2 will receive immunotherapy (atezolizumab) alone. Group 3 will receive the same immunotherapy as in Group 2, but in addition they will also receive chemotherapy and bevacizumab, which will be combined with the atezolizumab. The type of chemotherapy you will receive is a combination called FOLFOX which includes 5-fluorouracil (5-FU), leucovorin, and oxaliplatin. Bevacizumab, a biologic therapy, is routinely added to FOLFOX. NOTE: there was previously a Group 1 in this study who did not receive any immunotherapy and instead received the standard chemotherapy and bevacizumab. This treatment group is no longer an option based on new scientific information recently made available.

How long will I be in this study?

You will receive atezolizumab (Group 2) or atezolizumab with 5-FU, leucovorin, oxaliplatin and bevacizumab (Group 3). If you are in Group 3, for as long as you continue to benefit or as long as your doctors think it is safe to keep you on therapy, you will continue on treatment with 5-FU, leucovorin, and bevacizumab. Oxaliplatin will continue up to a total of 10 cycles in this group.

In either group, you will receive atezolizumab for up to 2 years.

If you stop study treatment for any reason, your study doctor will see you about 1 month after you stop to check for any side effects that you may be having. If your cancer has not progressed (grown) at the time you stop study treatment, you will continue to have scans until your cancer grows or until you begin another treatment for your cancer. After that, the researchers who are conducting this study would like to know how you are doing about every 6 months from the time you stop study therapy through about 5 years from when you joined the study. This can be done at a visit to your study doctor or by a phone call from your study team.

Are there side effects?

FOLFOX, bevacizumab, and atezolizumab may cause side effects. Your doctor will review all of the potential side effects with you. It is important to tell your doctor about any side effects during the study so that they may be treated and so that potential adjustments to the study drugs 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)

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