



Do you have locally advanced rectal cancer that is MSI-H (microsatellite instability-high) or dMMR (deficient mismatch repair)?

If so, you may be able to participate in this study of a potential new treatment.

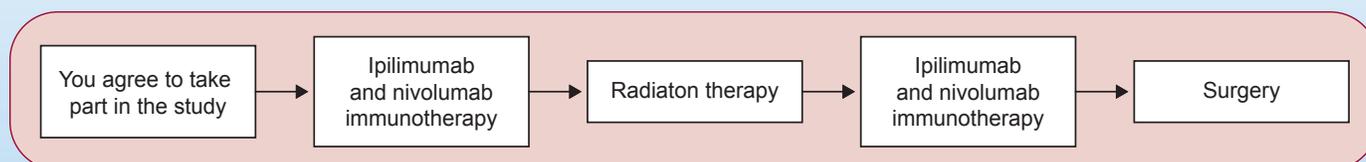
Testing Nivolumab and Ipilimumab with Short-Course Radiation in Locally Advanced Rectal Cancer

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for treating rectal cancer.
- The usual approach for patients with rectal cancer is treatment with radiation, surgery, and chemotherapy.
- The purpose of EA2201 is to find out if the addition of two immunotherapy drugs, nivolumab and ipilimumab, to radiation (prior to surgery) will lower the chance of your rectal cancer growing/spreading, and cause fewer cancer cells to be found at the time of surgery than would normally be found after chemoradiation and/or chemotherapy.
 - Immunotherapy drugs like nivolumab and ipilimumab stimulate the body's immune system to help the body fight cancer.

WHAT does this study involve?

- If you decide to participate in EA2201, you will get:
 - Immunotherapy with nivolumab and ipilimumab (through a vein in the arm, or through a port) for two 28 day cycles, then
 - Short-course radiotherapy (5 days), followed by
 - Two additional 28-day cycles of immunotherapy with nivolumab and ipilimumab, followed by
 - An assessment of how your cancer has responded to treatment by using a digital rectal exam (DRE), CT scan, and magnetic resonance imaging (MRI)
 - Surgical resection of your cancer, referred to as total mesorectal excision (TME)
- Your doctor will continue to follow your condition closely for at least 5 years. You will have:
 - Blood tests every 3 months for 2 years, and every 6 months for 3 additional years
 - Scans at least annually for 5 years
 - A colonoscopy 1 year after surgery, then every 3–5 years after that
- You can decide to stop taking part in the study at any time, even after you have enrolled.





WHO will take part in this study?

- Approximately 31 patients will participate in EA2201.
- Participants must have stage II or III rectal cancer that is MSI-H (microsatellite instability-high) or dMMR (deficient mismatch repair).
- Participants must not have previously received chemotherapy/immunotherapy for their rectal cancer, or radiotherapy to the pelvis.

WHAT are the costs of taking part in this study?

- Just as you would if you were getting the usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study. Check with your insurance company to find out what they will pay for.
- You/your insurance provider will **not** have to pay for the nivolumab and ipilimumab while you take part in this study. However, you/your insurance company will have to pay for preparing and administering the drugs.

IF you would like to know more

- About the EA2201 study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA2201, then select the link to EA2201
 - » For information about medical facilities where the study is available, scroll down the page to Locations and Contacts.
 - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- About clinical trials:
 - General cancer information: visit the NCI website at www.cancer.gov
 - Insurance coverage: visit www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
 - Visit www.ecog-acrin.org
 - For a list of patient resources and links to patient advocacy groups, visit <https://ecog-acrin.org/patients/resources>

