



Do you have anal cancer that has spread to other parts of your body (also known as metastatic anal cancer)?

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

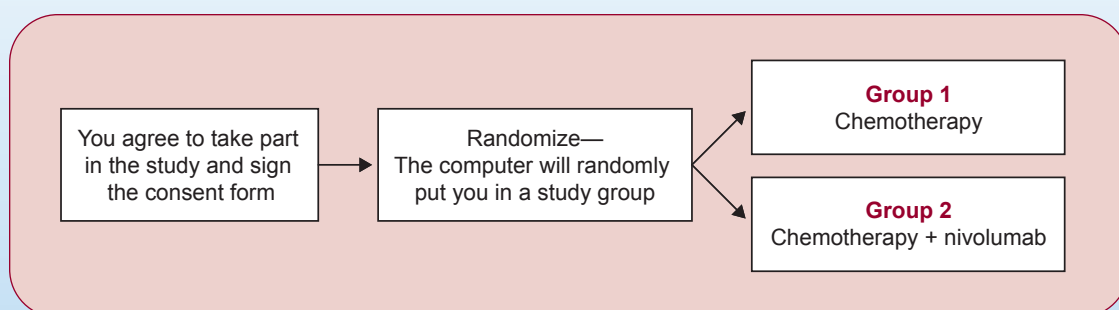
Testing the Addition of Nivolumab to Chemotherapy for Patients with Metastatic Anal Cancer

WHY consider participating in this study?

- Research studies are conducted to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.
- The purpose of the EA2176 study is to compare chemotherapy alone (this is the standard treatment for metastatic anal cancer) to chemotherapy plus immunotherapy (nivolumab). Immunotherapy is a type of cancer treatment that helps your immune system fight cancer. This study will help the study doctors find out if chemotherapy plus immunotherapy helps reduce symptoms and stop your cancer from growing.
 - Nivolumab is already approved by the Food and Drug Administration (FDA) for use in other cancers (including lung, skin, kidney, bladder, colorectal, and some liver cancers), but it is not currently FDA-approved to use with other drugs for the treatment of metastatic anal cancer.

WHAT does this study involve?

- If you decide to take part in EA2176, you will be assigned by chance (randomized) to one of the two groups listed below. The EA2176 randomization is 2 to 1, which means you will have twice the chance of receiving the immunotherapy (nivolumab).
 - **Group 1 (about 68 participants):** You will get the standard chemotherapy drugs used to treat this type of cancer, which are carboplatin and paclitaxel. You will get these drugs by vein (intravenously). You will receive carboplatin every 28 days, and paclitaxel on days 1, 8, and 15 of a 28-day schedule.
 - **Group 2 (about 137 participants):** You will get an immunotherapy study drug called nivolumab plus the standard of care chemotherapy drugs, carboplatin and paclitaxel. All of these drugs will be given intravenously. Nivolumab will be given on days 1 and 15 of the first 4 weeks, then it will be given on day 1 every 4 weeks until your cancer gets worse. You will receive carboplatin every 28 days, and paclitaxel on days 1, 8, and 15 of a 28-day schedule.





- Treatment for both groups will continue for 6 months. After the 6 months, patients in Group 2 will continue to receive nivolumab until your cancer gets worse or up to 2 years.
- After you finish your assigned treatment, your doctor will continue to follow your condition for up to 2 years. You will visit the clinic once every 3 months for the first year, then every 6 months for the second year.
- 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 205 people will take part in EA2176.
- Participants must be at least 18 years old with anal squamous cell carcinoma that:
 - Cannot be treated by surgery, *or*
 - Has come back, *or*
 - Has spread to other parts of the body
- Participants must not have had prior:
 - Immunotherapy
 - Systemic chemotherapy or other investigational drugs for the treatment of their anal cancer

WHAT are the costs of taking part in this study?

- You/your insurance provider will **not** have to pay for the nivolumab while you take part in EA2176. However, you/your insurance plan will have to pay for the costs of getting nivolumab, carboplatin, and paclitaxel ready and giving it to you.
- 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.

IF you would like to know more

- About the EA2176 study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA2176, then select the link to the EA2176 Home Page.
 - » If you are seeking information about the locations where the study is available, scroll down the page to Locations and Contacts and click the + sign.
 - 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>

