



Have you had surgery for squamous cell carcinoma of the head and neck (HNSCC) that has come back?

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

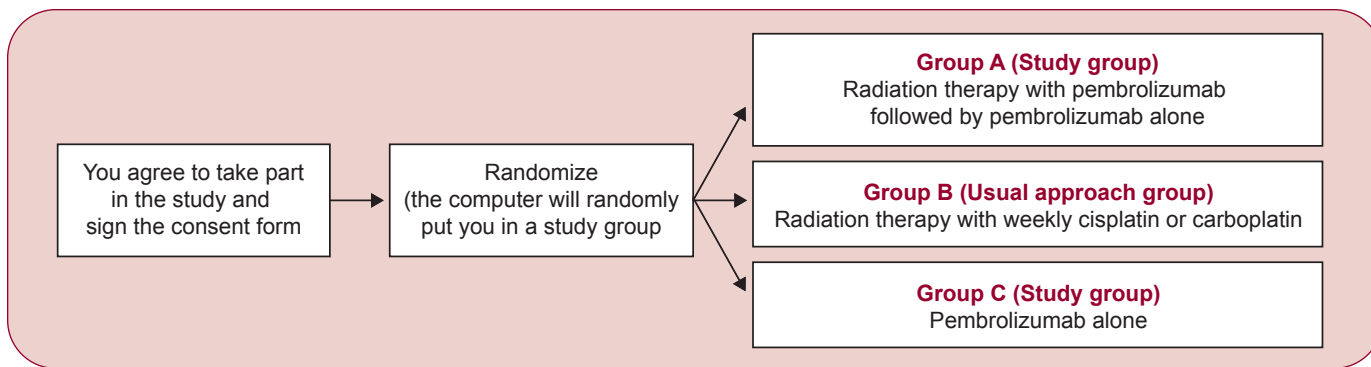
Testing What Happens When an Immunotherapy Drug (Pembrolizumab) is Added to Radiation or Given by Itself Compared to the Usual Treatment of Chemotherapy with Radiation after You have had Surgery for Your Recurrent HNSCC

WHY consider participating in this study?

- Research studies are done to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.
- EA3191 is evaluating if you will live longer after surgery if 1) an immunotherapy drug called pembrolizumab is added to radiation treatment or 2) if pembrolizumab is used by itself without radiation treatment.
- Immunotherapy drugs like pembrolizumab can produce an immune response that may help your body fight cancer. The purpose of EA3191 is to discover if this approach of using pembrolizumab is better or worse than the usual approach.
 - One usual approach for this type of cancer after surgery is to give radiation with chemotherapy. This can reduce the likelihood of the cancer recurring in the head and neck area, but it has not been proven to make you live longer.
 - Pembrolizumab is approved by the Food and Drug Administration (FDA) to treat HNSCC that has come back or spread to other parts of the body. Currently, it is approved for patients who are not able to undergo surgery or radiation.

WHAT does this study involve?

- If you decide to take part in EA3191, you will be assigned by chance (randomized) to one of the three groups below. You will have an equal chance of being in Group A, B, or C. (Note: the radiation being used with chemotherapy [Group B] will be the same as the radiation being used with pembrolizumab [Group A]).
 - **Group A:** You will get radiation for about 6 weeks (Monday–Friday) plus the study drug called pembrolizumab for up to 12 months. Pembrolizumab will be given by vein (intravenously) every 6 weeks for 9 doses.
 - **Group B:** You will get radiation for about 6 weeks (Monday–Friday) with chemotherapy (cisplatin or carboplatin intravenously once a week) for about 6 weeks. This is considered the usual approach to treat your type of cancer.
 - **Group C:** You will get pembrolizumab intravenously every 6 weeks for up to 12 months.



- You will be monitored closely by your doctor once you decide to take part in EA3191.
 - You will be followed for 5 years after starting the study. A study nurse/doctor will call you every 6 months to see how you are doing.
- 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 282 people between ages 18 and 79 will take part in EA3191.
- Participants must have HNSCC that has come back, or have a new head and neck cancer in a different area of the head/neck. Furthermore, participants must have surgically removed their cancer and had radiation to the area.

WHAT are the costs of taking part in this study?

- You/your insurance provider will **not** have to pay for pembrolizumab (if randomized to Group A or C). However, you/your insurance plan will have to pay for the costs of getting the pembrolizumab 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.
 - For Group B, you/your insurance provider will have to pay for the chemotherapy you would receive (cisplatin or carboplatin) and the cost of getting it ready and giving it to you.
- Check with your insurance company to find out what they will pay for.

IF you would like to know more

- About the EA3191 study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA3191, then select the link to the EA3191 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>

