



If you are having surgery for sinonasal cancer, consider the EA3163 study

Frequently Asked Questions

What is the EA3163 study?

EA3163 (“Testing the Addition of Chemotherapy to the Treatment of Cancer of the Sinonasal Area”) is seeking to find out whether receiving chemotherapy treatment *before* your surgery for your sinonasal cancer may be beneficial for: (1) preservation of your eye or skull bone; (2) improving the chance of surviving the cancer.

Why is this study important to me and patients like me?

Currently, the standard care for nasal and paranasal sinus squamous cell carcinoma (NPNSCC) is surgery followed by radiation therapy. Surgery can result in the need to sacrifice the eye or skull bone. The EA3163 study is based on some encouraging results from smaller studies for patients who received chemotherapy before surgery (also known as *neoadjuvant chemotherapy*). However, a larger, randomized study like this one is needed to determine whether adding chemotherapy will improve the chances of survival or lead to a lower chance of needing surgery to the eye or skull bone.

What will happen if I choose to participate in this study?

If you are receiving this information, it means your doctor thinks you may be eligible for the EA3163 study. If you agree to participate, a computer will randomly assign you to one of two treatment groups:

- Group 1: Usual Care: surgery followed by radiation therapy (you will receive treatment for close to 10 weeks)
- Group 2: Chemotherapy (docetaxel and cisplatin or docetaxel and carboplatin) followed by the usual surgery and radiation therapy (you will receive treatment for close to 20 weeks)
- Patients with cancer cells present on the border of tissue removed during surgery or in their lymph nodes will receive postoperative radiation therapy + weekly chemotherapy.

For the EA3163 study, there are some extra tests that you will need to have if you choose to participate. The details regarding these tests can be found in the study consent form.

What are the differences between Group 1 and Group 2?

Both groups provide patients with the current standard of care for patients with sinonasal cancer, which is surgery followed by radiation. If you are assigned to Group 1 (no chemotherapy), this approach may be less toxic and/or produce fewer long-term side effects, but it also may not. Likewise, if you are assigned to the experimental group (Group 2), adding chemotherapy, which has not been approved to treat this type of cancer, may lead to a higher chance of organ preservation and/or lead to an improved chance of survival, but it also may not. Thus, doctors currently don't know whether the Group 1 or Group 2 approach is the better option for patients with sinonasal cancer; it is hoped that the results of this trial will help them to answer this very important question.

Are there risks to being in the EA3163 study?

Even if you are not on a study, there are risks associated with cancer treatment. All of the possible risks are clearly stated in the study consent form. If you are selected, your doctor will carefully monitor for any side effects that you may experience during this study and will provide supportive therapy to help manage them. If you are selected for Group 2 (chemotherapy) and you experience toxicities from the chemotherapy, your drug doses may be adjusted or discontinued. Your doctor will continue to watch you for side effects and follow your condition for a total of 5 years.

What are the costs of taking part in this study?

The routine costs of the care required in clinical studies are usually covered by health insurance; however, coverage may not be the same from plan to plan, so please discuss these issues with your healthcare provider and your insurer.

What should I do if I'm interested?

For more information about the EA3163 study, talk with your doctor, or:

- Visit www.ecog-acrin.org and search EA3163, then select the link to EA3163. If you are seeking information about medical facilities where the study is available, scroll down the page to Locations and Contacts
- Call the NCI Cancer Information Service: 1-800-422-6237

