

EA3231 Study

Study of Optimal Targeted Therapy Sequencing in Patients with Thyroid Cancer



If you have thyroid cancer that has worsened during or after your most recent cancer treatment, you may be eligible to participate in this study.

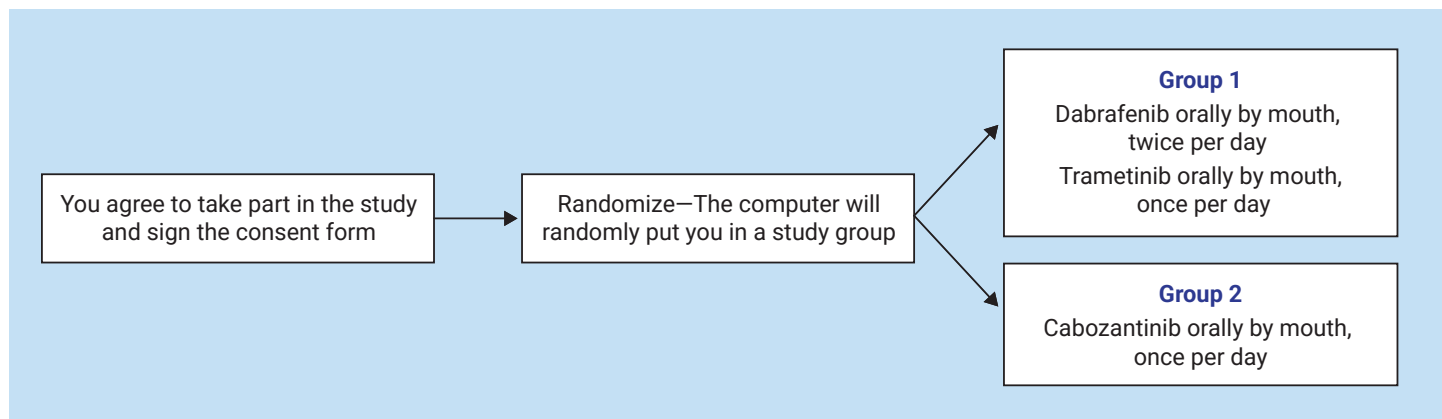
WHY CONSIDER PARTICIPATING IN THIS STUDY?

- Research studies are an important way to test the effectiveness of new therapies and approaches to treating cancer.
- The usual approach (i.e., the standard treatment most patients receive) for thyroid cancer that has worsened during or after initial treatment is therapy with Food and Drug Administration (FDA)-approved targeted therapies, such as dabrafenib and trametinib (usually given together) or cabozantinib.
- The purpose of EA3231 is to find out which FDA-approved targeted therapy works better to help control the cancer and keep it stable for longer: cabozantinib or the combination of dabrafenib and trametinib.

WHAT DOES THIS STUDY INVOLVE?

If you are eligible for this study and choose to participate:

- You will be randomized (randomly assigned by a computer) to one of two groups. You will have an equal chance of being in either group:
 - **Group 1** (about 66 people): Participants will receive dabrafenib and trametinib. Both medications are given as pills taken orally (by mouth); dabrafenib twice per day and trametinib once per day.
 - **Group 2** (about 66 people): Participants will receive cabozantinib, given as a pill taken orally once per day.
- Participants in both groups will keep a medication diary to help keep track of when the pills are taken. The diary should be brought to each clinic visit.
- After treatment begins, your doctor will check your condition at weeks 2, 4, 8, and 16. After that, your doctor will monitor you every 12 weeks for as long as you are receiving study treatment.



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- Cancer treatments can cause side effects. Your study doctor will review possible side effects with you, and you can ask questions about them at any time.
- Both groups will receive treatment until their cancer worsens or side effects become too severe. Further treatment will then be decided by your doctor.
- After you finish the assigned study treatment, your doctor will continue to watch you for side effects and follow your condition for up to 5 years from the date you registered for the study.

WHO WILL TAKE PART IN THIS STUDY?

- Up to 132 people with differentiated thyroid cancer (with a *BRAF V600E* mutation) that worsened during or after their most recent cancer treatment will take part in EA3231.
- Patients must have also already received treatment with lenvatinib or sorafenib to participate in this study.
- You can decide to stop taking part in this study at any time, for any reason, even after you have enrolled.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

- Just as if you were receiving 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 will receive as part of EA3231. This includes:
 - The costs of tests, exams, procedures, and medications that you get during the study to monitor your safety, and prevent and treat side effects
 - The costs of dabrafenib and trametinib or cabozantinib
- You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only, or that are covered by the study. Talk to your insurance provider to find out what they will pay for. If you are unsure which costs insurance will cover, ask your doctor or nurse for help finding the right person to talk to.
- Taking part in EA3231 may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer.
- You will not be paid for taking part in EA3231.

If you would like more information:

- About the EA3231 study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA3231, then select the link to the EA3231 page.
 - » If you are seeking information about the locations where this 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/paying for cancer treatment: 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 www.ecog-acrin.org/patients/resources