

EA6191/BAMM2 Study



Do you have advanced BRAF^{V600E/K} melanoma?

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

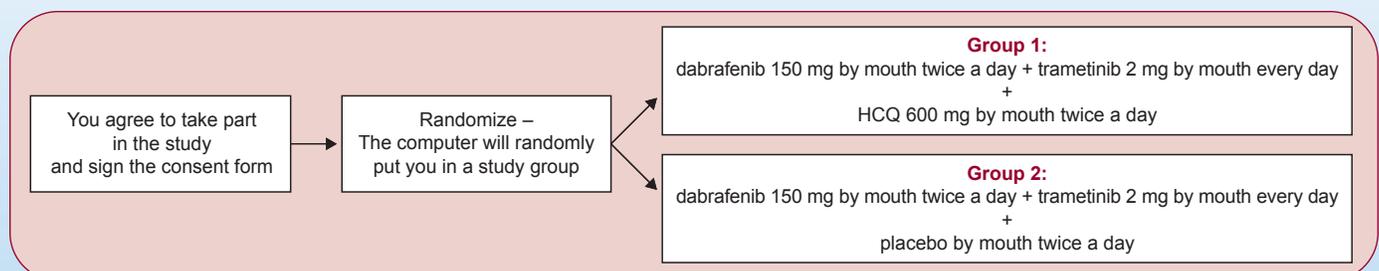
Testing the Combination of Dabrafenib and Trametinib with or without Hydroxychloroquine (HCQ) in Patients with Advanced Melanoma with Elevated Lactate Dehydrogenase (LDH)

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.
- EA6191/BAMM2 is being done to find out if adding HCQ to dabrafenib in combination with trametinib will significantly extend the length of time that your melanoma is well-controlled.
 - The purpose of the EA6191/BAMM2 study is to discover if this approach is better or worse than the usual approach. A usual approach for patients with advanced melanoma who are not in a study consists of oral medications that target the BRAF pathway (e.g., dabrafenib plus trametinib).
 - » Dabrafenib plus trametinib is FDA approved for the treatment of stage III and stage IV melanoma which carries a mutation in the BRAF gene.
- EA6191/BAMM2 is based on the findings of the BAMM study, which tested dabrafenib, trametinib, and HCQ in patients with stage IV BRAF mutant melanoma.
 - Although, the BAMM study was not specifically designed to look at patients with elevated LDH, the response rate and length of benefit when HCQ was added, seemed to be better than when these patients were treated with dabrafenib and trametinib alone.

WHAT does this study involve?

- If you decide to take part in EA6191/BAMM2, you will be assigned by chance (randomized) to one of the two groups listed below. Neither you nor your doctor will be told which group you are in, but your doctor can find out if it is necessary to know for your health.
 - **Group 1:** You will get usual drugs used to treat this type of cancer, dabrafenib (150 mg twice a day) plus trametinib (2 mg once a day), plus a study drug called HCQ (600 mg twice a day). These drugs are pills that you will take by mouth.
 - **Group 2:** You will get dabrafenib (150 mg twice a day) plus trametinib (2 mg once a day), plus a placebo pill (twice a day). A placebo pill looks like the study drug, HCQ, but contains no medication. These drugs/placebo are pills that you will take by mouth.





- You will be given study treatment for up to 24 months until your cancer becomes worse or the side effects are too severe. If treatment is successful, a portion of your treatment may be extended beyond 24 months.
- After you finish your assigned treatment, your doctor will continue to follow your condition for 6 months. You will be expected to visit your doctor every 2 months for 6 months and may be contacted by phone one year from starting treatment.
- 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 84 people will take part in EA6191/BAMM2.
- Participants must be at least 18 years old with:
 - Stage IIIC to stage IV melanoma that:
 - » Is not capable of being surgically removed
 - » Has spread from where it started to nearby tissue or lymph nodes
 - BRAF^{V600E} or BRAF^{V600K} tumor genotype
 - Elevated serum LDH
- Participants must have been treated with prior immune checkpoint inhibitor therapy (e.g., anti PD-1 and/or anti-CTLA-4).

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. This includes the cost of dabrafenib and trametinib. Check with your insurance company to find out what they will pay for.
- You/your insurance provider will **not** have to pay for HCQ or the placebo pill. However, you/your insurance plan will have to pay for the costs of getting the dabrafenib, trametinib, and HCQ/placebo ready and giving it to you.

IF you would like to know more

- About the EA6191 study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA6191, then select the link to EA6191
 - » If you are seeking information about the locations 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>

