EA2251 Study

If you have been diagnosed with advanced biliary tract cancer, you may qualify for a clinical study of a potential new treatment.

Testing the Addition of Ivonescimab Combined With Standard Chemotherapy Compared to the Usual Chemotherapy and Immunotherapy Treatment for Patients With Advanced Biliary Tract Cancer

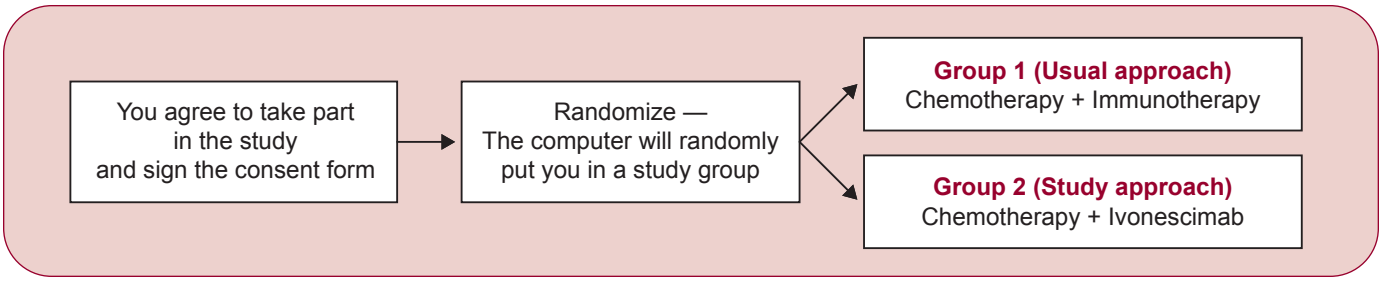
WHY consider participating in this study?

- 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 advanced biliary tract cancer (cancer that has spread beyond where it started or cannot be treated with surgery), is therapy with Food and Drug Administration (FDA)-approved:
  - Chemotherapy (such as gemcitabine and cisplatin), and
  - Immunotherapy (such as durvalumab or pembrolizumab).
    - » Immunotherapy can produce an immune response that may help the body fight cancer.
- The purpose of EA2251 is to test which approach is more effective and helps patients with advanced biliary tract cancer live longer:
  - The standard treatment (chemotherapy and immunotherapy), or
  - The standard chemotherapy and ivonescimab immunotherapy.
    - » Ivonescimab not only helps the body target cancer cells, but also cuts off blood supply to tumors, preventing them from growing. It has shown promising results in other types of cancer, but it is not yet known if it will benefit people with advanced biliary tract cancer.

WHAT does this study involve?

- If you are eligible for this study and choose to participate, you will be assigned (randomized) by a computer to one of two groups. You will have an equal chance of being in Group 1 or Group 2:
  - **Group 1** (usual approach; about 168 people): If you are in this group, you will get the usual chemotherapy (gemcitabine and cisplatin) and usual immunotherapy (durvalumab or pembrolizumab) used to treat advanced biliary tract cancer. These medications will be given through a vein (IV) in your arm for up to 6 months.
    - » After 6 months, you will continue with maintenance treatment using the immunotherapy drug you already received (durvalumab or pembrolizumab), with or without gemcitabine (per your doctor's decision).
      - Maintenance treatment will continue for up to 2 years after you started treatment, or until side effects become too severe or your cancer worsens.
  - **Group 2** (study approach; about 168 people): If you are in this group, you will get the usual chemotherapy (gemcitabine and cisplatin) used to treat advanced biliary tract cancer, plus ivonescimab immunotherapy. These medications will be given by IV for up to 6 months.
    - » After 6 months, you will continue with maintenance treatment using ivonescimab, with or without gemcitabine (per your doctor's decision).
      - Maintenance treatment will continue for up to 2 years after you started treatment, or until side effects become too severe or your cancer worsens.
- If you are assigned to Group 2, you will need to have blood samples taken about 6 times throughout the duration of treatment. Your blood samples will help researchers measure the amount of ivonescimab in your blood and see how your cancer responds to it.

EA2251 Study



- 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.
- For both groups, your condition and any side effects will be monitored:
  - Every 3 months for the first 2 years after you started treatment, then
  - Every 6 months for up to 3 years after joining the study.

WHO will take part in this study?

- Approximately 336 people with advanced biliary tract cancer (including cholangiocarcinoma and gallbladder cancer) will take part in EA2251.
  - Participants must not have received treatment for their current advanced biliary tract cancer.
- 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 EA2251. 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 cost of getting the study medications ready and giving them to you.
- If you are assigned to Group 2, you or your insurance provider will **not** have to pay for the ivonescimab while you take part in this study.
- Check with 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 EA2251 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 this study.

IF you would like more information:

- About the EA2251 study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EA2251, then select the link to the EA2251 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

NCI National Clinical Trials Network

ECOG-ACRIN cancer research group