EA2234/STOPGAP 2 Study

Do you have gastric cancer that has spread to the abdominal cavity?

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

Testing the Addition of Paclitaxel Administered Into the Abdominal Cavity Combined With Chemotherapy for Patients With Gastric Cancer Spread to the Abdominal Cavity

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 gastric cancer is treatment with Food and Drug Administration (FDA)-approved chemotherapy such as fluorouracil, leucovorin, capecitabine, oxaliplatin, and paclitaxel.
  - Immunotherapy medications such as nivolumab and pembrolizumab, and targeted drugs (i.e., trastuzumab), have also been approved by the FDA in addition to chemotherapy, and are now part of standard treatment.
- The purpose of EA2234, also known as STOPGAP 2, is to test which approach is better at lowering the chance that your cancer will grow/spread. It also aims to determine which treatment may help you live longer:
  - The usual approach, or
  - Administering paclitaxel chemotherapy directly into your abdominal cavity in addition to chemotherapy.

WHAT does this study involve?

- If you are eligible for this study and choose to participate, you will first receive a surgical procedure called a diagnostic laparoscopy. This will help the study doctors learn more about your gastric cancer.
  - Laparoscopy is a minimally invasive surgery for which you will be placed under general anesthesia. The surgeon will make small incisions (5mm) on your belly through which a camera and thin instruments are inserted to evaluate the abdomen.
  - This procedure takes about 1 hour to complete, and your study group will be assigned during the laparoscopy (you will not know which group you are in until after the surgery):
    - » **If you are assigned to Group 1 (about 74 people)**, you will not get an intraperitoneal port (a small device which is placed under the skin and fat of your upper abdomen with a tube placed into the abdomen).
    - » **If you are assigned to Group 2 (about 74 people),** you will have an intraperitoneal port placed, which will be used to deliver the paclitaxel directly inside your abdomen.
    - » Note: There is a very small chance that during the laparoscopy, the doctor might find something called “intra-abdominal adhesions”, which are areas of scar tissue. If this scar tissue prevents the surgeon from being able to place a port, you will not be able to participate in the study, but you will be able to receive the usual treatment for your cancer.
- Once you have fully healed from the laparoscopy, you will start study treatment. Depending on the group you are in, you will receive either:
  - **Usual Approach:** A standard chemotherapy regimen, chosen by you and your doctor, given through a vein in your arm (intravenously) and/or orally (Group 1), or
  - **Study Approach:** Paclitaxel through a tube in your belly plus chemotherapy given intravenously (Group 2).
  - Participants in both groups may also receive immunotherapy or targeted treatments as prescribed by your doctor.
- All participants will get treatment for 3 months, after which you will undergo re-evaluation. If your disease is under control or responding to treatment, you may continue the assigned treatment until your disease gets worse or any side effects become too severe. You may also be offered a surgical procedure to remove the cancer (if the amount of cancer is low and can be completely removed).

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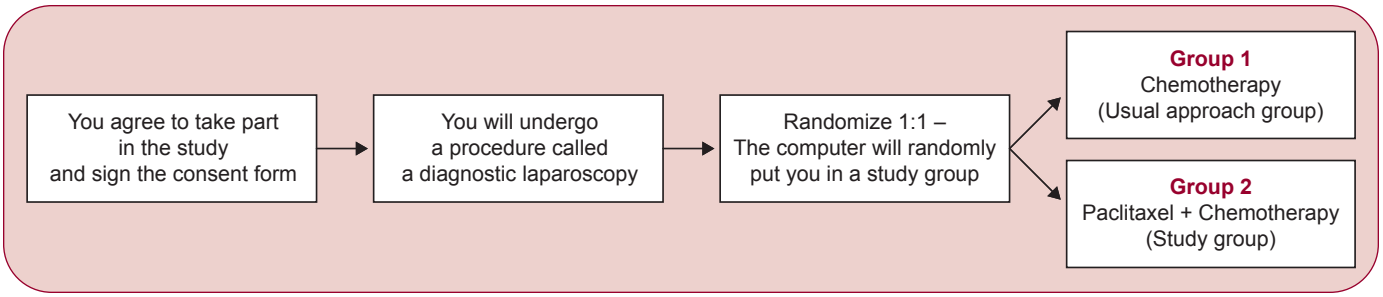

- Cancer treatments can cause side effects. Your study doctor will review possible side effects with you, and you can ask questions about them at any time.
- For both groups, after you finish your study treatment, your doctor will continue to monitor your condition for 5 years after you started the study.
  - Your doctor will follow you every 3 months for the first 2 years and every 6 months for years 3–5. You may be re-evaluated with chest/abdomen/pelvis imaging scans every 3–6 months for up to 5 years, if decided by your doctor.

WHO will take part in this study?

- Approximately 148 people whose gastric cancer has spread to the abdominal cavity will take part in EA2234/STOPGAP 2.
  - Participants must have received a minimum of 3 months and a maximum of 6 months of initial treatment.
  - Participants with microsatellite instability-high/mismatch repair deficient (MSI-H/dMMR) disease are not eligible for 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 EA2234. 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 paclitaxel and chemotherapy ready and giving them to you.
- You 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.
  - This includes the paclitaxel (if you are in Group 2) given through intraperitoneal port.
- 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 EA2234/STOPGAP 2 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 EA2234/STOPGAP 2 study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EA2234, then select the link to the EA2234 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