EA2185 Study: Pancreatic Cyst Screening

STUDY TITLE: Comparing Two Methods to Follow Patients with Pancreatic Cysts

CLINICALTRIALS.GOV STUDY NUMBER: NCT04239573

STUDY PHASE: Phase 3

WHAT ARE PANCREATIC CYSTS?
Pancreatic cysts are growths found on or within the pancreas that are filled with fluid. Cysts are often identified during routine imaging. There are several different types of cysts. Most pancreatic cysts are not cancerous and therefore do not need to be surgically removed unless something about that cyst becomes worrisome during follow-up screening exams, since the surgical removal of the cyst can have associated risks.

WHAT HAPPENS IN THIS STUDY?
Currently, there are two different standard follow-up screening schedules used by physicians to keep a check on the pancreatic cyst after it is initially identified. At present, it is not known which of these two schedules is better for the patient. This study will evaluate which of the two standard follow-up screening schedules will lead to better outcomes for patients with pancreatic cysts. In both schedules, the cyst will be followed with imaging scans called computerized tomography (CT) or magnetic resonance imaging (MRI). When needed, an endoscopic ultrasound* (EUS) is performed. The difference between the schedules is in the frequency of the follow-up screenings.

WHAT WILL THIS STUDY MEAN FOR PATIENTS?
Patients who are interested in participating in this study will be contributing to pancreatic cyst and cancer research. This research study may one day decrease the number of major and potentially risky pancreatic surgical procedures performed unnecessarily and help improve the early detection of potential pancreatic cancer.

Patients participating in this study will be assigned to one of the two standard follow-up screening groups. This assignment occurs by chance (randomized) through a computer, and neither the doctor nor the patient can choose the screening group. If at any time during the study, the patient’s doctor is concerned that the cyst may be cancerous, they may recommend to have a biopsy and possibly surgery. Patients participating in this study will also be asked to complete questionnaires about their emotional well-being and costs associated with these approaches, so the researchers can learn more about how pancreatic cysts affect people.

“There are two standard methods used to follow patients with pancreatic cysts. Both work well, but have important differences in cost, convenience, and maybe outcomes for cyst patients. This study is designed to figure out which method is better.”

-David Weinberg, MD
Fox Chase Cancer Center

“I have been through many methods of surveillance—some fairly invasive. Not all pancreatic cysts are cancerous, but once discovered, they need to be watched, as early detection can bring a better outcome. The results of this study will shed light on whether a less invasive surveillance schedule produces the same results, and patients who join this study will help determine this. It’s an important step forward for early detection, and if it can be easier on the patient, that’s even better.”

-Lisa Beckendorf
Patient Advocate and Survivor

*EUS is not used for routine follow-up screening. It is an investigational procedure used in the study.
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The following diagram explains the follow-up screening schedule for each study group:

**WHO IS ELIGIBLE?**

Men and women may be eligible if they are between the ages of 50 and 75, and have been diagnosed with a pancreatic cyst by imaging or EUS in the past 6 months.

They are not eligible if they have a history of acute or chronic pancreatitis, have had pancreatic surgery or their immediate family has history of pancreatic cancer.

**WHERE CAN I FIND MORE INFORMATION ABOUT THIS STUDY?**

- Visit [www.ecog-acrin.org](http://www.ecog-acrin.org) and search EA2185, then select the link to EA2185. Speak with your health care provider or call the National Cancer Institute at 1-800-4-CANCER (1-800-422-6237).

- STUDY LOCATIONS: This study is offered at many sites across the country. To find a research site near you or get contact information for a study location, go to [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and search using [NCT04239573](https://clinicaltrials.gov/ct2/show/NCT04239573).

*EUS involves insertion of a thin tube into the mouth, down into the stomach and into the first part of the small intestine. At the tip of the tube is a small ultrasound probe that emits sound waves. These sound waves bounce off of the surrounding structures, and are then recaptured by the probe and converted into images that are interpreted by the doctor. Because the pancreas sits next to the stomach and small intestine, EUS allows the physician to get very detailed images of the pancreas. This procedure is done under sedation in an outpatient setting.