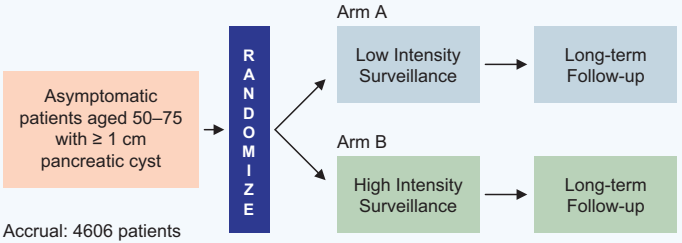
EA2185

Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs

Overall EA2185 Study Objective

To compare the clinical effectiveness and associated resource utilization of low intensity surveillance (similar to AGA) and high intensity surveillance (similar to Fukuoka) for pancreatic cyst surveillance

Study Schema



Study Objectives

Primary Objective

- Compare the rates of the following clinical outcomes across study arms:
  - Any pancreatic cancer without surgery
  - Unresectable pancreatic cancer or cancer >T1a, N0 at surgery
  - Benign disease at surgery

(Continued)

Study Objectives (cont.)

Secondary Objectives

- Clinical:
  - To compare rates of major surgical morbidity and/or mortality between arms
  - To compare pancreatic cancer incidence and all-cause mortality across arms
- Healthcare Resource Utilization and Costs:
  - Compare institutional (direct) costs, patient (out-of-pocket and other indirect) costs, and healthcare utilization of imaging, invasive testing, surgical, and other procedures across the two surveillance arms
  - Describe diagnostic test and treatment pathways by arm
- Patient Reported Outcomes:
  - Compare patient reports of QOL, situational anxiety, and financial distress
- Compare rates of non-adherence by arm assignment
- Correlative Biomarker Endpoint:
  - To evaluate and compare the predictive performance of known and future biomarkers for pancreatic cyst progression including cancer development
- Radiomic Endpoint:
  - To evaluate and compare the predictive accuracy of known and future radiomic markers for pancreatic cyst progression including cancer development

Eligibility Criteria*

Main Inclusion Criteria

- Age ≥ 50 years and ≤ 75 years
- Received a CT, MRI, or EUS within 6 months prior to randomization that revealed one or more ≥ 1 cm pancreatic cyst(s)

Main Exclusion Criteria

- Acute pancreatitis or a history of chronic pancreatitis
- Prior diagnosis of pancreatic malignancy of any type
- Patients with *only* pancreatic lesions without malignant risk (pancreatic pseudocyst or classic serous cystic lesion) are not eligible.
- 1st degree family history of pancreatic adenocarcinoma
- Pancreatic cyst morphology prompting immediate surgery
- Must not be participating in any form of pancreatic cyst surveillance
- Comorbid illness that precludes pancreatic cyst resection

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*When evaluating patients for this study, please refer to the full protocol for the complete list of eligibility criteria.

NCI Community Oncology Research Program

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