Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs

Overall EA2185 Study Objective
To compare the clinical effectiveness and associated resource utilization of high intensity surveillance (similar to Fukuoka) and low intensity surveillance (similar to AGA) for pancreatic cyst surveillance

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

Study Schema

- Asymptomatic patients aged 50–75 with ≥ 1 cm pancreatic cyst
- Accrual: 4606 patients
- Randomize

Step 1
- Arm A: Low Intensity Surveillance → Long-term Follow-up
- Arm B: High Intensity Surveillance → Long-term Follow-up

(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 or MRI within 3 months of registration that revealed a newly identified ≥ 1 cm pancreatic cyst

Main Exclusion Criteria

• Acute pancreatitis or a history of chronic pancreatitis
• Prior diagnosis of pancreatic cyst or pancreatic malignancy of any type
• Other asymptomatic pancreatic cystic lesion with zero/low malignancy potential on index CT/MRI
• 1st degree family history of pancreatic adenocarcinoma
• Pancreatic cyst morphology prompting immediate surgery
• 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.