

For Patients with Pancreatic Cysts**EA2185 Available Through ECOG-ACRIN Cancer Research Group**

Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs

Patient Population

See Section 3.0 for Complete Eligibility Details

- Must be ≥ 50 years and ≤ 75 years of age
- Must not have acute pancreatitis or a history of chronic pancreatitis
- Must have received a CT, MRI, or EUS within 6 months prior to randomization that revealed one or more ≥ 1 cm pancreatic cyst(s)
- Patients of childbearing potential must not be known to be pregnant
- Must not have a prior diagnosis of pancreatic malignancy of any type
- Must not have a history of pancreatic resection
- Patients with only pancreatic lesions without malignant risk (pancreatic pseudocyst or classic serous cystic lesion) are not eligible
- Must not have a family history of pancreatic adenocarcinoma in one or more first-degree relatives (biological parents, full siblings or children)
- Must not have pancreatic cyst morphology that would prompt immediate surgical consideration (enhancing mural nodule, solid component in cyst, pancreatic duct ≥ 10 mm, cyst causing obstructive jaundice)
- Must not have a comorbid illness that precludes EUS or pancreatic cyst resection
- Must not be currently participating in pancreatic cyst surveillance defined as organized, periodic up-to-date imaging directed towards the pancreatic cyst of interest

Surveillance Plan

See Section 5.0 for Surveillance Plan

Arm A– low intensity surveillance:

- Pre-enrollment imaging (MRI or CT or EUS) within 6 months prior to study randomization
- MRI/CT (preferably same imaging modality) in 1 year from pre-enrollment imaging
- If EUS is indicated by imaging features (at any point) and the subsequent EUS does not indicate surgery, repeat MRI/CT in 1 year. If EUS is not indicated on a follow-up MRI/CT study, repeat the MRI/CT in 2 years
 - ◇ See protocol for EUS indication parameters
- Diagnostic EUS expected within 2 months of surveillance CT/MRI

Arm B– high intensity surveillance:

- Pre-enrollment imaging (MRI or CT or EUS) within 6 months prior to study randomization
- Schedule next imaging from time of pre-enrollment imaging by specific schedule per protocol
- Frequency of surveillance is determined based on largest/most suspicious cyst at each evaluation
 - ◇ **Cyst ≥ 1 and < 2 cm:** CT/MRI every 6 months for 1 year, then every 12 months for 2 years, then increase interval to 24 months
 - ◇ **Cyst ≥ 2 and < 3 cm:** EUS within 6 months of pre-enrollment CT/MRI/EUS. If EUS negative repeat in 1 year. If next EUS negative, alternate CT/MRI and EUS every 12 months
 - ◇ **Cyst ≥ 3 cm:** Alternate CT/MRI with EUS every 3-6 months
- See protocol for EUS indication parameters; diagnostic EUS within 2 months of surveillance CT/MRI
- If size of the cyst has changed and EUS is not indicated, the timing of the next surveillance scan will be determined by the new size (if < 1 cm, CT/MRI in 6 months, then every 2 years if no change)

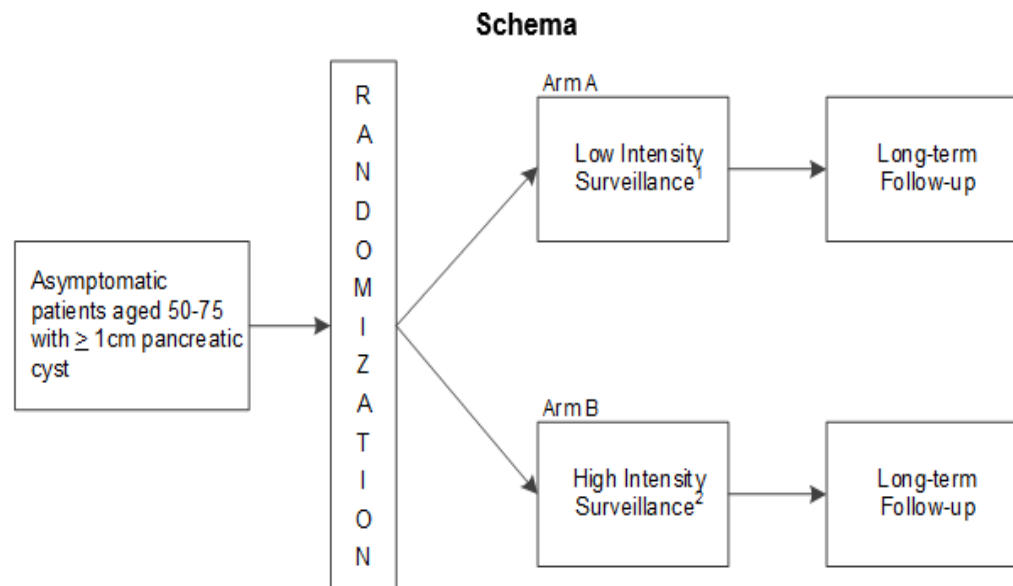
Note: Patients meeting the indications for surgery but refuse surgery or are deemed inappropriate surgical candidates will remain on the protocol surveillance assigned at randomization

Patient EnrollmentAll Sites: Oncology Patient Enrollment Network (OPEN), <https://open.ctsu.org/open>**Protocol Information**ECOG-ACRIN Operations-Boston: 857-504-2900, <http://ecog-acrin.org> (Member Login)**Please Enroll Your Eligible Patients!****Study Chair:**David S. Weinberg, MD,
MSc**Co-Chairs:**Herbert Zeh, MD
Paul Moayyedi, MD
James Scheiman, MD

EA2185

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Accrual: n = 4606

1. Low Intensity Surveillance:

- Pre-enrollment imaging (MRI or CT or EUS) study within 6 months prior to study randomization
- Repeat MRI/CT imaging (preferably same imaging modality) in 1 year
- If no abnormalities on year 1 study, repeat every 2 years
- If EUS is indicated by imaging features (at any point) and the subsequent EUS does not indicate surgery, repeat MRI/CT in 1 year. If imaging does not indicate EUS, then extend the interval to two years.

2. High Intensity Surveillance

- Pre-enrollment imaging (MRI or CT or EUS) study within 6 months prior to study randomization
- Subsequent evaluation depends upon index cyst size
 - Cyst ≥ 1 and < 2 cm: CT/MRI every 6 months for 1 year, then every 12 months for 2 years, then increase interval to 24 months
 - Cyst ≥ 2 and < 3 cm: EUS within 6 months of pre-enrollment CT/MRI/EUS. If EUS negative repeat in 1 year. If next EUS negative, alternate CT/MRI and EUS every 12 months.
 - Cyst ≥ 3 cm: Alternate CT/MRI with EUS every 3-6 months