

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 pancreatic cyst resection
- Must not be participating in any form of pancreatic cyst surveillance

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
- Repeat MRI/CT (preferably same imaging modality) in 1 year; if no abnormalities, 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, extend interval to 2 years
 - ◊ See protocol for EUS indication parameters

Arm B– high intensity surveillance:

- Pre-enrollment imaging (MRI or CT or EUS) 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
 - ◊ See protocol for EUS indication parameters

Note: Patients who develop a pancreatic lesion appropriate for resection but refuse surgery or are deemed inappropriate surgical candidates will remain on the protocol surveillance assigned at randomization

Study Chair:

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Co-Chairs:

Herbert Zeh, MD
Paul Moayyedi, MD
James Scheiman, MD

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN), <https://open.ctsu.org>

Protocol Information

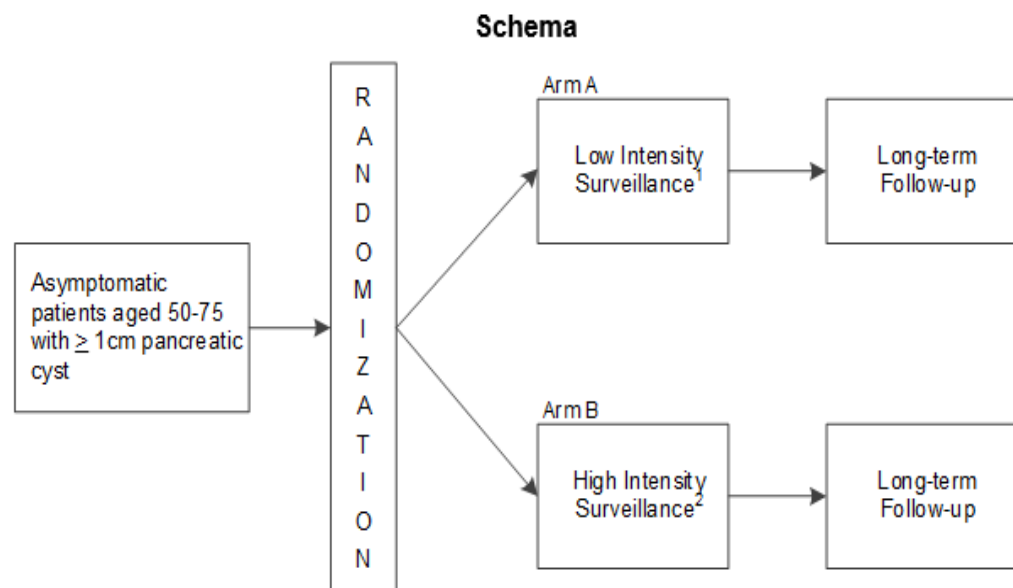
ECOG-ACRIN Operations-Boston: 857-504-2900, <http://ecog-acrin.org> (Member Login)

Please Enroll Your Eligible Patients!

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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