For Patients with Pancreatic Cysts

EA2185 Available Through ECOG-ACRIN Cancer Research Group
Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs

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**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 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

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

**Protocol Information**

Please Enroll Your Eligible Patients!
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Schema

Asymptomatic patients aged 50-75 with ≥ 1 cm pancreatic cyst

Randomization

Arm A
Low Intensity Surveillance
Long-term Follow-up

Arm B
High Intensity Surveillance
Long-term Follow-up

Accrual: n = 4606

1. Low Intensity Surveillance:
   - Pre-enrollment imaging (MRI or CT or EUS) study within 6 months prior to study randomization
   - Repeat MR/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