

Biospecimen Collection to Identify Gene Mutations for High Risk Pancreatic Cancer in Pediatric Patients, INSPPIRE 2 Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: Up to 17 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- All subjects/parents must sign an informed consent and/or assent indicating that they are aware of the investigational nature of this study
- Subjects/parents must have signed an authorization for the release of their or their child's protected health information
- All children must be under 18 years of age at the time of enrollment
- All children providing samples should fit the ARP or CP inclusion criteria defined below:
 - Acute pancreatitis (AP): AP is defined as requiring 2 of the following:
 - Abdominal pain compatible with AP
 - Serum amylase and/or lipase values ≥ 3 times upper limits of normal
 - Imaging findings of AP, such as gland enlargement, acute inflammatory changes, and fluid collections
 - ARP is defined as: At least 2 episodes of acute pancreatitis with complete resolution of pain and a ≥ 1 month pain-free interval between episodes
 - Chronic Pancreatitis:
 - One irreversible structural change in the pancreas with or without abdominal pain +/- exocrine pancreatic insufficiency +/- diabetes
 - Irreversible structural changes:
 - Ductal calculi, dilated side branches, parenchymal calcifications found in any imaging (abdominal ultrasound [abd US], magnetic resonance imaging/magnetic resonance cholangiopancreatography [MRI/MRCP], computerized tomography [CT], endoscopic retrograde cholangiopancreatography [ERCP], endoscopic US [EUS])
 - Ductal obstruction or stricture/dilatation/irregularities that are persistent (for ≥ 2 months) on any imaging
 - Parenchymal atrophy, irregular contour, accentuated lobular architecture, cavities alone are not diagnostic findings for CP
 - Surgical or pancreatic biopsy specimen demonstrating histopathologic features compatible with CP (acinar atrophy, fibrosis, protein plugs, infiltration with lymphocytes, plasma cells, macrophages)

Exclusion Criteria:

- Subjects must not have any significant medical illnesses that in the investigator's opinion cannot be adequately controlled with appropriate therapy or would compromise the subject's ability to tolerate study interventions

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration

Conditions:

Chronic Pancreatitis, Exocrine Pancreas Carcinoma, Recurrent Acute Pancreatitis

More Information

Description:

This clinical trial collects blood, saliva, urine, or stool samples to help identify possible genetic mutations that may increase a person's chance at developing pancreatic cancer. Finding genetic markers among pediatric patients with acute recurrent pancreatitis and chronic pancreatitis may help identify patients who are at risk of pancreatic cancer.

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Principal Investigator:

Principal Investigator ID:

Phase:

IRB Number:

System ID: NCT06651580

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