Diabetes RELated to Acute pancreatitis and its Mechanisms (DREAM)

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• Diagnosis of acute pancreatitis (AP) 0-90 days prior to enrollment date
• Participant fully understands and is able to participate in all aspects of the study, including providing informed consent, completion of case report forms (CRFs), telephone interviews, metabolic testing, and planned longitudinal follow-ups

Exclusion Criteria:

• Diagnosis of definite chronic pancreatitis (CP) at enrollment based on either of the following criteria met by computed tomography (CT) scan (including non-contrast enhanced) or Magnetic resonance Imaging (MRI) or Magnetic Resonance Cholangiopancreatography (MRCP): (a) Parenchymal or ductal calcifications on CT scan (after excluding the possibility that calcifications are vascular); (b) Intraductal filling defects suggestive of calcifications on MRI and/or MRCP
• Potential participants with post-endoscopic retrograde cholangiopancreatography (post-ERCP) AP who are hospitalized for <48 hours.
• Prior (i.e., before enrollment) direct endoscopic necrosectomy of the pancreas or percutaneous necrosectomy or drainage of necrotic collection(s). Participants who require this during follow-up will remain in the study
• Pancreatic tumors, including ductal adenocarcinoma, neuroendocrine tumors, and metastasis
• Confirmed or suspected cystic tumor associated with main pancreatic duct dilation, or believed to be the cause of AP (in the site-PI's judgement)
• Prior pancreatic surgery, including, but not limited to: distal pancreatectomy, pancreaticoduodenectomy, pancreatic necrosectomy, Frey procedure
• Use of disallowed concomitant medications within 30 days prior to enrollment. A comprehensive list of disallowed medications will be included and routinely updated in the study's Manual of Procedures
• Severe systemic illness that in the judgement of the investigative team will confound outcome assessments of DM and immunological outcomes or pose additional risk for harms, including: history of solid organ transplant, acquired immunodeficiency syndrome (AIDS), active treatment for cancer (except non-melanoma skin cancer) within 12 months prior to enrollment, chronic kidney disease with estimate glomerular filtration rate (eGFR) < 30 or on dialysis prior to AP, and cirrhosis (based on imaging or biopsy), or any other medical condition that in the opinion of the site-PI carries a life expectancy of <12 months.
• Known pregnancy at the time of enrollment. Participants who become pregnant during follow-up will remain in the study, but may have modified study assessments for safety
• Incarceration
• Any other condition or factor that would compromise the participant's safety or the scientific integrity of the study

Conditions & Interventions

Conditions:
Acute Pancreatitis, Diabetes & Endocrine, Digestive & Liver Health
Keywords:
Diabetes

Description: The purpose of this research study is to find out how many people with acute pancreatitis develop diabetes. Risk factors for diabetes and the types of diabetes that occur after acute pancreatitis will also be studied. A small number of people who already had diabetes before their acute pancreatitis attack will be enrolled for comparison. Diabetes is a known complication of acute pancreatitis. Diabetes can last a few weeks after acute pancreatitis and get better. Diabetes may not improve after acute pancreatitis. It can also appear a year or more after acute pancreatitis. Little data is available on diabetes after acute pancreatitis. This study will help us better understand diabetes after acute pancreatitis and who is at increased risk of developing it, as well as the different types of diabetes. We are asking participants to take part in this research study who have recently had an acute pancreatitis attack. Participants may be on this study for up to 5 years. There is a screening/enrollment visit, a metabolic visit and 5 year follow-up period. If you had diabetes before your acute pancreatitis attack, your study participation will end after the enrollment visit. If you did not have diabetes before your acute pancreatitis attack, you will return to the clinic for up to 6 more visits. An additional two visits can be done either at the clinic or by phone. If you are diagnosed with diabetes during the follow-up period, you will be asked to come in for an additional visit.

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Phase: NA
IRB Number: STUDY00013389
System ID: NCT05197920

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