

A Randomized Trial of Intra-Portal Alone Versus Intra- and Extra- Portal Transplantation of Pancreatic Islets After Total Pancreatectomy for Chronic Pancreatitis

Status: Recruiting

Eligibility Criteria

Sex: All

Age: 18 Years to 68 Years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Age 18-68 2. Scheduled for total pancreatectomy and IAT at U of MN. All patients who are approved for pancreatectomy and IAT at U of MN are reviewed by a multi-disciplinary committee including surgeons, gastroenterologists specializing in pancreatic disease, a pain specialist psychologist, and endocrinologist to confirm the diagnosis of chronic pancreatitis and candidate suitability for surgery. 3. Able to provide informed consent

Exclusion Criteria:

1. Pre-Existing diabetes mellitus fasting blood glucose >115mg/dl, or hemoglobin A1c level >6.0% because these are all evidence of inadequate beta-cello mass. 2. Use of any of the following treatments in the 30 days prior to enrollment: insulin, metformin, sulfonylureas, glinides, thiazolidinediones, GLP-1 agonists, DPP-4 inhibitors, or amylin. 3. ALT or AST >2.5 times the upper limit of normal (ULN). Bilirubin >ULN, unless due to benign diagnosis such as Gilbert's. 4. Any of the following hematologic abnormalities: server anemia (hemoglobin <10 g/dL), thrombocytopenia (<150/mm³), or neutropenia (<1.0 x 10⁹/L). 5. Current use or expected use of oral or injected corticosteroids, or any medication likely to affect glucose tolerance. However, use of hydrocortisone for physiologic replacement, or use of any topical, inhaled or intranasal glucocorticoid is permitted. 6. Current or expected use of any other immunosuppressive agent. 7. Known coagulopathy, or need for anticoagulant therapy preoperatively (coumadin, enoxaparin), or any history of pulmonary embolism. 8. For females, plans to become pregnant or unwillingness to use birth control for the study duration. 9. Inability to comply with the study protocol. 10. Untreated psychiatric illness that may interfere with ability to give informed consent, or other developmental delay or neurocognitive disorder that impairs with a patient's ability to consent on their own behalf. 11. Any other medical condition that, in the opinion of the investigator, may interfere with the patient's ability to successfully and safely complete the trial.

Conditions & Interventions

Interventions:

Procedure: Intrahepatic islets and islets in the omental pouch, Procedure: Intrahepatic islets alone, Other: Normal Volunteers

Conditions:

Chronic Pancreatitis, Diabetes Mellitus, Islet Cell Transplantation

Keywords:

total pancreatectomy with islet autotransplant, Clinics and Surgery Center (CSC)

More Information

Description: One treatment for certain types of chronic pancreatitis is total pancreatectomy with islet autotransplantation (TPIAT). In this procedure, the pancreas is removed (eliminating the source of the pain) and the islets, which produce insulin and other important hormones, are taken from the pancreas and transplanted in to the liver. This is a small study to evaluate a new procedure for transplanting some islets to a new location in the body.

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Phase: N/A

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