Clinical outcome after total pancreatectomy with islet autotransplantation

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The goal of this study is to monitor the long-term islet function after total pancreatectomy with islet autotransplantation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON55170

Source
ToetsingOnline

Brief title
TOPPER

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Endocrine gland therapeutic procedures

Synonym
chronic pancreatitis, islet transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Afdelingsfonds eilandjes

Intervention

Keyword: islet, pancreatectomy, pancreatitis, transplantation

Outcome measures

Primary outcome

AUC0-120min C-peptide (nmol/L/120min) during a mixed meal tolerance test (MMTT).

Secondary outcome

- Maximum C-peptide concentration (nmol/L) during the MMTT
- Difference in basal and maximum C-peptide (nmol/L) during the MMTT
- Time below target range range (<3.9), in target range (3.9-10) and hyperglycemic range (>10.0) determined by flash glucose measurement (FGM) or continuous glucose measurement (CGM)
- Standard deviation determined by flash glucose measurement (FGM) or continuous glucose measurement (CGM) during the follow-up period
- HbA1c in blood and estimated by FGM or CGM
- Insulin requirements (assessed as the average IU/kg/day during the last week)
- Quality of life assessed by MOS Short Form 36 (SF-36) and EQ-5D
- Diabetes related stress assessed by Problem Areas in Diabetes Questionnaire (PAID)
- Exocrine pancreatic insufficiency assessed by Pancreas Exocrine Insufficiency Questionaire (PEI-Q)
- Pancreas-related pain assessed by COMPAT-SF questionnaire and Izbicki questionnaire
- Quantitative Sensory Testing

- Use of opioids assessed in Morphine Milligram Equivalents

- Degree of change in pancreatic tissue assessed by histologic examination for fibrosis, acinar cell atrophy, inflammation and nesidioblastosis, characterized as absent or rare, moderate, numerous.

- Frequency of surgical complications (early <3 months after TPIAT, late >3 months after TPIAT).

- Frequency of complications attributed to islet transplantation.

- Patient characteristics

Study description

Background summary

A total pancreatectomy with islet auto transplantation (TPIAT) can be performed for a number of indications, such as idiopathic chronic pancreatitis, pancreas divisum with recurrent pancreatitis, hereditary pancreatitis and trauma.
The most common indication is chronic pancreatitis which is a condition characterized by recurring inflammation of the pancreas. The condition is characterised by severe abdominal pain, it progresses and leads to permanent damage of the pancreas affecting the exocrine and endocrine function. The endocrine function is responsible for glucose regulation by secretion of the hormones insulin and glucagon by the islets of Langerhans.
In the current standard of treatment, after non-invasive and endoscopic efforts to relieve the pain, a total pancreatectomy is a last resort option. The pancreas is surgically removed during this procedure. Afterwards, the patient will have diabetes mellitus that is usually difficult to control and the patient will be dependent on exogenous insulin administration.
TPIAT is a total pancreatectomy that is followed by islet isolation from the resected pancreas and autotransplantation of these islets into the liver by means of a transhepatic intraportal islet infusion. Depending on the number and quality of islets, TPIAT may lead to full islet function so that no anti-hyperglycemic therapy is necessary or to partial islet function necessitating anti-hyperglycemic therapy. This can be only oral agents with reasonable islet function or complex insulin regimes with poor islet function. However, even with partial islet function, glycemic control is easier with a lower risk of hypoglycemic events and diabetes-related complications, and an

overall improvement of quality of life.

Study objective

The goal of this study is to monitor the long-term islet function after total pancreatectomy with islet autotransplantation.

Study design

This study is an observational cohort study. All patients will receive the same treatment (TPIAT) as if they would not participate in this study. Data are collected on endocrine function at baseline and postoperatively in the first 3 months and then yearly up to 15 years. Parallel to those visits, questionnaires will be conducted to evaluate pain, quality of life, stress and exocrine pancreatic insufficiency. Data on complications after total pancreactomy and islet autotransplantation will be collected. Quantitative Sensory Testing will be conducted at baseline and 6 months after TPIAT.

Study burden and risks

For this study, participants will have 2 extra visits to the hospital for quantitative snesory testing. This is a noninvasive test where the participants may experience pain shortly. They will also fill out questionnaires periodically. These questionnaires are not burdensome.

This is a low-risk study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 16 years
- Referred for TPIAT or TPIAT performed since 2014
- Active and/or passive understanding of the Dutch language
- Willingness to wear a flash glucose measurement or continuous glucose measurement device at least in the first 3 months after TPIAT and for 2 weeks before yearly study visits

Exclusion criteria

- Known malignancies of the pancreas

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2022
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	15-02-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74838.058.21