Assessing and predicting functional and quality of life-related outcomes of islet and pancreatic transplantation in patients with type 1 diabetes mellitus

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON43807

Source
ToetsingOnline

Brief title
Outcomes of islet and pancreatic transplantation

Condition

- Diabetic complications
- Psychiatric and behavioural symptoms NEC
- Endocrine gland therapeutic procedures

Synonym
Diabetes, transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: DCTI;diabetesfonds

Intervention

Keyword: Diabetes mellitus, Islet transplantation, Pancreas transplantation, Quality of life

Outcome measures

Primary outcome

The study endpoint for the first objective is allograft function (as assessed

by mixed meal test and beta score) at 1 and 5 years, together with serum beta

cell damage markers

Secondary outcome

Quality of life

Hypoglycemia burden

Study description

Background summary

There is need for specific markers to predict pancreas and islet graft function and damage on the short and long term after pancreas or islet transplantation; no validated markers currently exist and therefore allograft rejection is generally not recognized in time. In the long term graft function deteriorates; we cannot currently predict at which time this happens and the exact cause is not known. Research is hampered due to lack of data on predictors and aetiology. Also, clinical pancreas or islet transplantation does not always lead to insulin independence in patients with type 1 diabetes. Pancreas transplantation has better long term results concerning insulin independence, but is associated with more complications on the short term. Islet transplantation has fewer complications but achieves insulin independence in fewer cases. Despite the fact that insulin independence is often not achieved in most islet transplant recipients, there is a large reduction of episodes of severe hypoglycaemia and fewer diabetes-related complications as compared to before transplantation. We hypothesize that there will be a clear correlation between marker elevation

and allograft failureFurthermore, we hypothesize that quality of life will improve after both procedures, possibly more so on the short term for islet transplantation recipients and more so in the long term for pancreas transplantation recipients

Study objective

There are two objectives for this study: first, to find specific serum beta cell damage markers that can serve as a clinical predictive tool for beta cell allograft loss. Second, to compare quality of life and diabetes-related outcomes in patients who receive a pancreas versus an islet transplantation at the LUMC

Study design

Prospective observational cohort study
Before and after transplantation (+3, 12, 24, 60 months) allograft function will be determined with a mixed meal test (MMT). Also urine samples will be taken for kidney damage markers. Furthermore, three questionnaires will be administered (for quality of life (SF36), Clarke's hypoglycemia scoring list and the PAID (psychosocial aspects in diabetes). During follow-up serum markers for islet damage (micro-RNA panel, C-peptide, PPP1R1A, complement profile) will be measured in decreasing frequency and correlated to graft function.

Study burden and risks

The extent of the burden consists of one extra MMT before islet transplantation for the islet transplant recipients, and a total of 5 extra MMT*s (before and 3, 12, 24 and 60 months after transplantation) for the pancreatic transplantation recipients. Also, one extra instance of drawing blood is required (directly after transplantation). The other instances of blood drawing are timed at the outpatient clinic visits. The risk is considered to be negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Accepted for either islet or whole pancreas transplantation at the LUMC or post transplantation.
Received either islet or whole pancreas tranplantation at the LUMC and are currently follow up by mixec meal tolerance test

Exclusion criteria

-Severe cognitive or psychiatric impairment
-Unable to adequately understand the Dutch language

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2016
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO

Date:	13-01-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-09-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	20-12-2016
Application type:	Amendment
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	NL54705.058.15