Fecal Microbiota Transplantation to Preserve Residual Beta Cell Function In Patients With Newly Diagnosed Type 1 Diabetes Mellitus

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26193

Source
Nationaal Trial Register

Brief title
The FMT-Preserve-DM1-trial

Health condition

type 1 diabetes

Sponsors and support

Primary sponsor: DFN/DON grant
Source(s) of monetary or material Support: DFN/DON grant

Intervention

Outcome measures

Primary outcome

Effect on residual beta cell function as measured by stimulated C-peptide response upon

mixed-meal tolerance (Boost) area under the curve (AUC0-120min) using a 2 hour mixed meal (MMT) test at 0, 6, 9 and 12 months.

Secondary outcome

Effect on Immunologic whole blood parameters (FACS) including circulating immune cell fractions and specifically measure T-cell exhaustion at 0, 6, 9 and 12 months. Also, we will use RNA seq to measure expression patterns in these cells to pinpoint which immune pathways are differentially expressed at these timepoints.

Effect on fecal microbiota composition (sequencing) and plasma and urine metabolites at 0, 6, 9 and 12 months.

Effects on the small intestinal microbiota composition as well as (histology) immunological and transcriptome changes in duodenal biopsies taken at 0 and 6 months.

Effect on clinical diabetes management(daily exogenous insulin dosage (IE/kg bw) and amount of hypoglycemia events, dietary intake and gastrointestinal complaints using questionaires at 0, 6, 9 and 12 months

Effect on glucose variability (HbA1c) as well as FreeStyle data (FSL determined time in range (TIR), hypo- and hyperglycemic episodes)measured with participants continuous glucose monitoring device at 0, 6, 9 and 12 months.

Study description

Background summary

To investigate whether fecal microbial transplantation (FMT) from donors with
type 1 diabetes and a highly preserved beta cell fraction versus placebo, administered every 8 weeks during
6 months through a small intestinal tube, preserves residual beta cell function and subsequent immunological tone up until 12
months after intervention in patients with newly diagnosed type 1 diabetes

Study objective

In this study we will investigate whether changes in gutmicrobiota composition induced by allogenic donor fecal transplantation (from longterm type 1 diabetes mellitus patients with preserved beta cell function) compared to placebo, , has beneficial effects on residual beta cell function and immune status in new onset type 1 diabetes mellitus patients. A parallel objective is to see which small (duodenal biopsy) and large intestinal (fecal samples) microbiota predict these clinical changes.

Study design

Primary endpoint:
Effect on residual beta cell function as measured by stimulated C-peptide response upon mixed-meal tolerance (Boost) area under the curve (AUC0-120min) using a 2 hour mixed meal (MMT) test at 0, 6, 9 and 12 months.
Secundary endpoints:
Effect on circulating immune cell fractions (FACS and RNAseq) and specifically measure T-cell exhaustion at 0, 6, 9 and 12 months.
Effect on fecal microbiota composition (sequencing) and plasma and urine metabolites (mass spect) at 0, 6, 9 and 12 months.
Effects on the small intestinal microbiota composition as well as (histology) immunological and transcriptome changes (gene expression) in duodenal biopsies taken at 0 and 6 months
Effect on clinical diabetes management(daily exogenous insulin dosage (IE/kg bw) and amount of hypoglycemia events, dietary intake and gastrointestinal complaints using questionaires at 0, 6, 9 and 12 months
Effect on glucose variability (HbA1c) as well as FreeStyle data (FSL determined time in range (TIR), hypo- and hyperglycemic episodes) measured with participants continuous glucose monitoring device at 0, 6, 9 and 12 months.

Intervention

allogenic donor fecal transplantation (from longterm type 1 diabetes mellitus patients with preserved beta cell function) versus placebo

Contacts

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Eligibility criteria

Inclusion criteria

patients with <6 weeks of new onset type 1 diabetes mellitus and detectable C-peptide levels (aged 18-65 years, BMI 18-30 kg/m2, male/females, no concomitant medication).

Exclusion criteria

• Inability to provide written informed consent
• Evidence for absent residual betacel function (undetectable C-peptide)
• Antibiotics use in the last 3 months and proton-pump inhibitor use
• Evidence for compromised immunity
• Second auto-immune disease (i.e. coeliac disease, hyper- or hypothyroidism, inflammatory bowel disease)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-05-2021
Enrollment:	34
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
n/a

Ethics review

Positive opinion

Date:	13-05-2021
Application type:	First submission

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
NTR-new	NL9488
Other	METC AMC : 2020_288

Study results

Summary results

n/a