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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26193

Bron
NTR

Verkorte titel
The FMT-Preserve-DM1-trial

Aandoening

type 1 diabetes

Ondersteuning

Primaire sponsor: DFN/DON grant
Overige ondersteuning: DFN/DON grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

AMC
max nieuwdorp

0031 20 5666612

Wetenschappelijk

AMC
max nieuwdorp

0031 20 5666612

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-05-2021
Aantal proefpersonen:	34
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
n/a

Ethische beoordeling

Positief advies

Datum:	13-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9488
Ander register	METC AMC : 2020_288

Resultaten

Samenvatting resultaten
n/a