Fecal Microbiota Transplantation to Restore Residual Beta Cell Function In Patients With Long- Duration Type 1 Diabetes Mellitus

No registrations found.

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

Summary

ID

NL-OMON27205

Source
Nationaal Trial Register

Brief title
FMT-Restore-DM1-trial

Health condition

type 1 diabetes

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Dutch Diabetes Foundation/DON

Intervention

Outcome measures

Primary outcome

residual beta cell function (measured with a mixed meal test) in relation to gut microbiota

composition changes at 6 months before treatments (run-in), at baseline, and at 6 and 12 months.

Secondary outcome

reduction in autoimmunity markers including FACS on peripheral blood lymphocyte subsets (change Th17 (CD4+IL-17+) and T-regs (CD4+CD25+ FoxP3+) and T-cell exhaustion at these timepoints. Finally, plasma metabolites are determined

Study description

Background summary

To investigate whether fecal microbial transplantation (FMT) from either allogenic donor (from type 1 diabetes with a highly preserved beta cell fraction) or autologous (own) donor restores residual beta cell function up until 12 months after intervention in patients with longstanding type 1 diabetes

Study objective

Does FMT improve residual beta cell function in longstanding DM1

Study design

6 months before treatments (run-in) as well as at baseline, and at 6 and 12 months after start of FMT treatment.

Intervention

multiple fecal transplantations from either donors (DM1 subjects with highly preserved beta cell function) or autologous feces

Contacts

Public
Amsterdam UMC
max nieuwdorp

0031 20 5666612
Scientific
Amsterdam UMC

max nieuwdorp

0031 20 5666612

Eligibility criteria

Inclusion criteria

• Patients with >5 years type 1 diabetes
• Aged 18-65 years
• BMI 18-30 kg/m2
• Male/females
• No concomitant medication besides exogenous insulin

Exclusion criteria

Inability to provide written informed consent
• Evidence for absent residual beta cel function (undetectable C-peptide in urine)
• 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:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	22-12-2020
Enrollment:	34
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	22-12-2020
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	NL9153
Other	METC AMC : 2020_225

Study results