Residual beta cell function and microbiome in type 1 diabetes

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25270

Source
NTR

Brief title
GUTDM1 cohort

Health condition

type 1 diabetes

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

associations between residual beta cell function (2-hour post-meal urinary C-peptide / creatinine ratio), gut microbiome composition and circulating T-cell immune cell function

Secondary outcome

Correlation of above mentioned primary endpoints with:
-Frequency of Hypoglycemia
• Awareness of hypoglycemia
• presence off Diabetic complications
• Circulating (T cell) immune cell panel including HLA type
• Fecal microbial composition (illumina 16s ribosomal RNA sequencing)
• Plasma microbial metabolomics
• Sex
• Age
• Duration of type 1 diabetes
• Smoking
• Medication use
• Diabetic complications
• Abdominal complaints
Recorded at the study visit
• Blood pressure
• BMI
• Glucose time in range from continuous glucose monitoring device (Free style libre) .
• Serum creatinine and calculated eGFR
• Lipid profile (total cholesterol, HDL, LDL triglycerids)
• urinary Albuminuria/creatinine ratio
• HbA1c
• CRP

Study description

Background summary

It has become apparent that most individuals with type 1 diabetes mellitus (T1D) have some remaining beta cell function. Individuals with T1D and a preserved beta cell mass have a lower risk of hypoglycaemia and diabetic complications. The factors regulating residual beta cell function are unknown. A likely mechanism leading to a large beta cell reserve is regulation of immunological tone by the gut microbiome. Therefore, we will investigate whether residual beta cell mass is associated with gut micro-biome composition and circulating immune cell counts in individuals with T1D.

Study objective

The association between the gut microbiome/virome, T-cell exhaustion and immuno-tolerance in T1D constitutes an important knowledge gap and may serve as a therapeutic target in T1D, that will be adressed in this cohort study.

Study design

1 day (only one study visit)

Intervention

none

Contacts

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Scientific
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Eligibility criteria

Inclusion criteria

All individuals with T1D visiting the outpatient clinic of recruiting centres in the greater Amsterdam region
>18 years old.

Exclusion criteria

- Active infection at the time of inclusion (not to influence immune-cell function)
• Antibiotic or proton-pump inhibitor use last 3 months (not to influence microbiome)
• Unwillingness to donate feces, urine and/or blood
• Inability to provide informed consent based on cognitive function, language barrier or other reasons
• Absence of large bowel (ie colostomy).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2020
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
n/a

Ethics review

Positive opinion

Date:	24-09-2020
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	NL8931
Other	METC AMC : 2020-105

Study results

Summary results
will follow