Microbiome Characteristics and short-chain FATty acid metabolism in type 1 diabetes patients versus healthy controls

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To investigate the differences in short-chain fatty acid metabolism, markers of local (intestinal) and systemic inflammation and markers of bacterial translocation between type-1-diabetes patients and healthy controls and to relate these differences...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON38809

Source
ToetsingOnline

Brief title
MCFAT

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Autoimmune disorders

Synonym
Diabetes type 1 /

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gut microbiome, inflammatory tone, short-chain fatty acids, type 1 diabetes

Outcome measures

Primary outcome

The primary study parameter will be short-chain fatty acids in feces and plasma (acetate, propionate, butyrate) in relation to glycemic control (HbA1c and daily insulin use) and plasma lipid profiles.

Secondary outcome

Secondary study parameters will be intestinal integrity and inflammatory tone (measured by fecal calprotectin), intestinal bacterial translocation (by plasma LPS-binding peptide) and plasma inflammatory markers (leukocytes, C-reactive protein). Gut microbiome differences which will be evaluated by HIT-chip and oral microbiome, obtained by oral mucosal swab and finally diet/caloric intake evaluated by 1 week diet lists.

Study description

Background summary

The gut microbiome and short-chain fatty acid metabolism have been associated with type 1 and type 2 diabetes. Children with beta-cell autoimmunity at risk of developing DM1 are characterized by decreased fecal concentrations of butyrate-producing bacteria, whereas absolute decreases in butyrate-producing bacteria concentrations were also reported in a small group of long term diagnosed DM1 patients. Furthermore, a recent mouse study points out that an interaction between the gut microbiome and the innate immune system is an essential factor in developing type 1 diabetes. In short, there are many clues in the literature that the gut microbiome not only influences metabolism, but also, through immune activation, invokes chronic inflammatory processes leading to insulin resistance and that it can trigger auto-immunity. Key processes here seem to be loss of bowel wall integrity, bacterial translocation and a deranged

fatty acid metabolism.

Study objective

To investigate the differences in short-chain fatty acid metabolism, markers of local (intestinal) and systemic inflammation and markers of bacterial translocation between type-1-diabetes patients and healthy controls and to relate these differences to variations in the intestinal microbiome.

Study design

Observational single centre study.

Study burden and risks

Burden: 1 time delivery of fecal and urine sample. 1 blood sampling concomitant with routine blood sampling on the outpatient clinic. Participants will be asked to fill out a diet list daily for 1 week prior to the visit.
Risks are a. the risk of a bruise from blood sampling and b. the finding of a previously unknown diseases. No other risks are associated with these procedures.

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

patients:
1. Definite diagnosis of type 1 diabetes i.e. positive auto-antibodies or unambiguous clinical picture
2. no concomitant medication (no statins, ACE/ATII inhibitors, PPI nor antibiotics)
3. Normal BMI: 18-25 kg/m2
4. A balanced, *western* diet (see appendix);healthy controls:
1. normal BMI
2. Caucasian
3. Balanced, 'western' diet

Exclusion criteria

patients:
1. Ambiguous clinical picture i.e. features of type 2, or other types of diabetes
2. Complications of diabetes (retinopathy/neuropathy/microalbuminuria)
3. Medication use (eg statins, ACE/ATII inhibitors, PPI).
4. Antibiotic use in the last three months
5. (Regular) use of probiotics-containing food
6. A diet that is one-sided or unusual (see appendix)
7. Medical conditions that can be expected to affect glucose metabolism or gut microbiome
8. Chronic diarrhea;Healthy controls:
1. Medication use
2. Comorbid conditions
3. Antibiotic use in the last three months
4. (regular) use of probiotics-containing food
5. A one sided or unusual diet
6. Diarrhea

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL44813.018.13