

Butyrate Use in TYPe 1 diabetes: effects on Regulation of bActerial translocation, innate immunity, T-cell function and Endotoxemia

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To investigate whether ingestion of 4 grams of butyrate daily during 4 weeks can positively affect the immune system function, residual betacell function and low grade inflammation in patients with type 1 diabetes mellitus.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON40633

Source

ToetsingOnline

Brief title

BUTYRATE

Condition

- Diabetic complications
- Autoimmune disorders

Synonym

diabetes, type 1 diabetes mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bacterial translocation, Butyrate, Glucose regulation, T-cell function

Outcome measures

Primary outcome

Changes in immunity signatures in peripheral blood: effect of butyrate on in monocyte-macrophage function and differences in in vitro (eg IL-6 cytokine production after bacterial stimuli)

Secondary outcome

- Changes in T cell autoimmunity parameters in peripheral blood FACS on peripheral leukocyte subsets (change in cytokine/Tr1/nTreg/Th2/Th17 subset population, cellular islet autoimmunity (CD4, CD8, GAD, IA2) and mucosa innate and adaptive immunity (CXCR3, β 7)
- Beta cell function (highly sensitive C-peptide in serum after standardized breakfast meal)
- Glucose regulation (HbA1c and daily insulin use)
- Intestinal and systemic inflammation (fecal calprotectin, CRP, leukocytes)
- Bacterial translocation (LPS-binding peptide in serum)
- Changes in fecal and serum short-chain fatty acids
- Changes in gut microbiome
- Caloric intake evaluated by 1 week diet lists before visits

Study description

Background summary

Regulation of diabetes has shown to be related to bowel wall integrity and bacterial translocation. Furthermore literature leads us to believe that the intestinal microbiome might be an important pathophysiological component, in its function or disability to provide required levels of the short-chain fatty acid butyrate. Finally, butyrate has been shown to affect innate immune system signatures (macrophage IL-6-production) and positively affect bowel wall integrity and glucose regulation in mice.

Study objective

To investigate whether ingestion of 4 grams of butyrate daily during 4 weeks can positively affect the immune system function, residual beta cell function and low grade inflammation in patients with type 1 diabetes mellitus.

Study design

Double blind randomized cross-over trial

Intervention

daily ingestion of 4 grams of sodiumbutyrate (butifar) or placebo

Study burden and risks

Daily ingestion of 4 grams of sodiumbutyrate (butifar) for one month was found to be safe in OBUGAT study I (MEC2013_239). No risks or adverse events were seen. Apart of vena punctie, no invasive procedures will be performed.

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

Type 1 diabetes (antiGAD en/of IA2 antibody positive)

normal body weight

normal diet

Exclusion criteria

relevant comorbidity

recent use of antibiotics

probiotic use

retinopathy, nephropathy or neuropathy

smoking

systemic medication use except insulin

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO	
Date:	21-11-2014
Application type:	First submission
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	NL50503.018.14