# 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 periferal 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 autoimmunityl parameters in periferal 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, 67)

- 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 betacell 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: Intervention model: Interventional

Parallel

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

### Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2015
Enrollment:	30
Туре:	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** CCMO ID NL50503.018.14