

A comparative study of the role of intestinal acetate production in human appetite and insulin secretion and insulin sensitivity

No registrations found.

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

Summary

ID

NL-OMON28226

Source

Nationaal Trial Register

Brief title

APRAISE study

Health condition

We will include subjects from the Amsterdam HELIUS study (n=6000) and include only those with 10% lowest and 10% highest fecal butyryl-coenzyme A transferase enzyme (based on previously obtained results of 16S analysis and cross-validated by qPCR butyryl CoA transferase) will be approached for this study.

Sponsors and support

Primary sponsor: AMC-UvA

Source(s) of monetary or material Support: AMC-UvA

Intervention

Outcome measures

Primary outcome

- differences in Postprandial plasma acetate levels after a SMMT
- differences in Baseline Intestinal microbiota composition (morning stool samples)
- differences in baseline Faecal acetate levels

Secondary outcome

- CNS (fMRI) responses to food pictures (BOLD) signal, i.e. in CNS activation in predefined regions (insula, striatum, amygdala, OFC, PFC, hippocampus and hypothalamus) in response to viewing food pictures or consuming actual food
- Insulin sensitivity measured as Matsuda's insulin sensitivity index during the standardized mixed meal test
- Insuline secretion measured as c-peptide response during the standardized mixed meal test
- Energy metabolism, measured by resting energy expenditure (REE)
- Baseline physical activity energy expenditure (PAEE)
- Dietary intake (<https://mijn.voedingscentrum.nl/nl/eetmeter>), weight and body composition (Body Impedance Analysis, BIA).
- Subjective appetite sensations and eating behavior (VAS questionnaires)

Study description

Background summary

We designed a comparative study to investigate whether a high intestinal acetate production is associated with altered acetate production and whether this affects insulin sensitivity and secretion as well as with neural responses to virtual and actual food stimuli (fMRI).

Study objective

In this study we aim to investigate whether intestinal acetate production by gutmicrobiota is related to (postprandial) plasma acetate levels, insulin secretion/sensitivity and the CNS regulation of food intake (fMRI).

Study design

1 day

Intervention

(high fiber) containing standardized mixed meal test

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Male or female
- Stable bodyweight (<5% reported weight change during the previous 3 months)
- Age 18-65 years
- Caucasian (i.e.: Dutch or Turkish nationality)
- Able and willing to give informed consent

Exclusion criteria

- Use of corticosteroids, antibiotics and other immunomodulating medication in last 3 months
- XTC, amphetamine, nicotine or cocaine abuse, based on the 20 item drug abuse screening test (DAST-20)
- Alcohol abuse (> 3 units per day)
- Contraindication for MRI (neurological illness , malignancy, history of major heart disease, history of major renal disease, pregnancy or breast feeding, pacemaker and metals contraindicated for MRI present in the body)
- Expected prolonged compromised immunity (due to recent cytotoxic chemotherapy or
- HIV infection with a CD4 count <240)
- Presence of inflammatory bowel disease (IBD)²
- Inability to understand the study protocol, give informed consent or participate adequately in study protocol

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	09-07-2018
Enrollment:	54
Type:	Anticipated

Ethics review

Positive opinion

Date: 09-07-2018

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	NL7131
NTR-old	NTR7328
Other	: METC 2018_053

Study results