De smaakbeleving van zoet en de samenstelling van mond- en darmflora bij mensen met (risico op) diabetes

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27844

Source
Nationaal Trial Register

Brief title
DiaBos

Health condition

diabetes
taste perception
microbiota

Sponsors and support

Primary sponsor: TNO
Utrechtseweg 48. NL-3704 HE Zeist
Source(s) of monetary or material Support: Sunstar Suisse SA
Route de Pallatex 11, 1163 Etoy, Switzerland

Intervention

Outcome measures

Primary outcome

Differences between control and diabetes patients in:

- sweet detection threshold

- composition and diversity of the oral and gut microbiota

Secondary outcome

Differences between control and diabetes patients in:

- metabolic response to sweet by the gut

- the ways in which the above three parameters (sweet detection threshold, microbiota and metabolic response) relate to each other.

Study description

Study objective

The main objective of this study is to determine whether prediabetic individuals and those already diagnosed with type 2 diabetes show differences in sweet taste perception and whether this difference is related to their oral and/or gut microbiota composition.

Study design

not applicable

Intervention

in part of the study steviol glycosides

Contacts

Public
Femke Rutters
Amsterdam
The Netherlands
Scientific
Femke Rutters
Amsterdam
The Netherlands

Eligibility criteria

Inclusion criteria

• Able to speak, write and understand Dutch

• Voluntary participation

• Provided written informed consent

• Willing to comply with the study procedures of phase 1 and phase 2

• Appropriate veins and circulation for blood sampling

• Willing to accept use of all nameless data, including publication(s), and the confidential use and storage of all data for at least 15 years

• Willing to accept the disclosures of the financial benefit of participation in the study to the authorities concerned

Exclusion criteria

• Any significant medical reason for exclusion as determined by the investigator

• Having a history of medical or surgical (gastrointestinal) events that may significantly affect the study outcome

• Smoking

• Other medication for diabetes than oral medication (i.e. Insulin)

• Recent antibiotic medication (in the last 3 months)

• Alcohol consumption > 21 units/week

• Unable to give written informed consent

• Not willing to give up blood donation during the study

• Not having a general practitioner

• Not willing to accept information transfer concerning participation in the study, or information regarding his health, like laboratory results, findings at anamnesis or physical

examination and eventual adverse events to and from his general practitioner

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46352
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7014
NTR-old	NTR7212
CCMO	NL63702.029.17
OMON	NL-OMON46352

Study results