Sweet taste perception in relation to mouth and intestinal microbiota in people with (risk of) Diabetes

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

Summary

ID

NL-OMON46352

Source
ToetsingOnline

Brief title
Diabetes oral sensing

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, T2D

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: interne financiering TNO;Strategische Middelen Onderzoek ,Sunstar Suisse SA

Intervention

Keyword: diabetes, microbiota, nutrient sensing, sweet taste

Outcome measures

Primary outcome

Primary study parameters/endpoints:

* Differences between control and diabetes patients in:

o sweet detection threshold

o composition and diversity of the oral and gut microbiota

Secondary outcome

Secondary study parameters/endpoints:

* Differences between control and diabetes patients in:

o metabolic response to sweet by the gut

o the ways in which the above three parameters (sweet detection threshold,

microbiota and metabolic response) relate to each other

Study description

Background summary

Diabetes is a worldwide problem with a heavy burden on healthcare costs and it is associated with a variety of complications. Previous research has shown that people with type 2 diabetes may have altered mechanisms of nutrient sensing, which interferes with the response of the body via metabolic, endocrine and neural changes. Nutrient sensing starts in the mouth and is then continued in the gut by taste perception via receptors. The detection of sweet taste determines metabolic responses such as glucose homeostasis and satiety hormone release. Alterations of these functions can contribute to the onset of diabetes and obesity. The oral and gut microbiota interacts with host metabolism and physiology in many different and complex ways, and is likely to play a role in nutrient sensing, taste detection and regulation of appetite.

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. The secondary objective of this study is to investigate to what extent oral and/or gut nutrient sensing of sweet impacts the entero-endocrine response.

Study design

The study will consist of two phases. In phase I, data on oral sweet taste perception and on oral and gut microbiota will be collected from a cohort of participants with type 2 diabetes (n=50), age and gender matched with non-diabetic controls (n = 50). In phase II, a subset of these participants (n = 20; 10 diabetes patients & 10 non-diabetic controls) will receive a mixed meal challenge in combination with oral or gastrointestinal priming with a sweetener or water, to determine the relation between nutrient sensing in the mouth and gut and the metabolic response of the gut.

Intervention

Phase I study: not applicable. Phase II study: steviol glycosides are administered to both groups.

Study burden and risks

We do not foresee specific risks for the participants in the study. Participants will be asked to visit the research centre once for phase I of the study, during which anthropometric measures and a taste detection threshold will be measured using non-invasive procedures. In Phase II participants will be asked to visit the centre three times, and each time blood will be collected. The remaining samples will be obtained through non-invasive procedures (faeces collection and buccal/tongue swab).

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

* 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:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2018
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

ID: 27844
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63702.029.17
OMON	NL-OMON27844