Kunnen zoetstoffen de bacteriesamenstelling in de mond verbeteren? De PROM studie

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23131

Source
Nationaal Trial Register

Brief title
PROM

Health condition

prevention of gingival inflammation and other oral diseases

Sponsors and support

Primary sponsor: ACTA Dental Research B.V.
Source(s) of monetary or material Support: ACTA Dental Research B.V.

Intervention

Outcome measures

Primary outcome

microbiome composition of dental plaque and tongue swabs before and after the 2-weeks challenge

Secondary outcome

the amount of red fluorescent plaque (RFP) before and after the 2-weeks challenge

Study description

Background summary

Rationale: From previous work done at our department, we expect that carbohydrates will steer the ecosystem away from proteolytic capacity which is associated with gum disease. Hence, it is interesting to investigate whether such a change in the oral ecology will occur. Because then an oral rinse of a carbohydrate sweetener dissolved in water may aid in the treatment of periodontal disease.

Objective: To study the effect of sweetener oral rinses on the oral microbiome composition.

Study design: Five groups of 14 people will use 3 times daily an oral rinse for 2 weeks (5 randomly assigned sweeteners: one sweetener per group). Subjects are seen 6 times in a period of 3 to 5 weeks including the screening visit. At the 6 visits, biological samples and data are collected: dental plaque samples, tongue swab sample, salivary pH is measured and QLF-photos are taken. DMFS is recorded once. The composition of individual oral bacterial communities will be determined using 16S rRNA amplicon sequencing. The data will be analysed using in house pipelines for microbial ecology analyses. We expect that the sweeteners will steer the ecosystem away from proteolytic capacity and hence will increase its resilience to gum disease.

Study population: Healthy, non-smoking volunteers, who are mentally-competent and ≥16 years old.

Intervention: An oral rinse containing a sweetener in water 3 times daily after the main meals.

Main study parameters: The main study parameter is the composition of the microbiome before and after the intervention. The secondary study parameter is the amount of red fluorescent plaque before and after the use of the prebiotic rinses.

Study objective

Previously, we have established that (i) healthy volunteers display different oral ecotypes and that (ii) these ecotypes are very likely indicative for the resilience (disease risk) of the oral cavity of these volunteers. Therefore, we want to embark on a next study in which the objective is to establish that modulation of the oral ecosystem strengthens oral resilience and supports oral health. In this clinical study prebiotic strategies in the shape of oral rinses of sweeteners dissolved in water will be evaluated on their potential to steer/switch the oral

ecotype as analyzed by its biomarkers.

Study design

Screening and 5 visits in 14 days

Intervention

an oral rinse of a sweetener in water, 5 carbohydrates (sweeteners) are selected and each rinse contains a 10% solution of the carbohydrate

Contacts

Public
ACTA
dr. C.M.C. Volgenant

+31205980596
Scientific
ACTA
dr. C.M.C. Volgenant

+31205980596

Eligibility criteria

Inclusion criteria

1. Healthy, ASA I as assessed by medical questionnaire
2. Non-smokers: definition non-smoker: <1 cigarette every day for at least one year3
3. Minimum of 20 natural teeth: at least 5 evaluable teeth in each quadrant
4. 17 – 50% bleeding on probing

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Smoker
2. Overt dental caries
3. DPSI ≥3+ - 4

4. Removable (partial) dentures
5. Removable night guard
6. Oral and/or peri-oral piercings
7. Apparent oral lesions (aphthous ulcers excluded)
8. Presence of orthodontic banding (except for lingual retention wire)
9. Participation in a clinical study within the previous 30 days
10. Great chewing-gum consumer > 3 gums a day

General health and use of medication:
11. Self-reported pregnancy or breastfeeding
12. Use of antibiotics during the last 2 months
13. Need of antibiotic prophylaxis prior to dental treatment. The use of anti-inflammatory drugs on a regular basis. Evidence of any systemic disease or compromised health condition
14. Adverse medical history or long-term prescribed medication (except for anti-contraceptives)
15. Allergic to soy(beans), milk, eggs, gluten or lupin(beans)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2019
Enrollment:	70
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48478
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7525
CCMO	NL68654.100.19
OMON	NL-OMON48478

Study results