Can sweeteners encourage the growth of good bacteria? A clinical exploratory pilot study.

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON48478

Source
ToetsingOnline

Brief title
PROM (PRebiotic function of sweeteners on Oral Microbiome)

Condition

- Bacterial infectious disorders

Synonym
gingivitis, gum disease

Research involving
Human

Sponsors and support

Primary sponsor: ACTA Dental Research B.V.
Source(s) of monetary or material Support: Consortium via Stichting LSH-TKI,GlaxoSmithKline,Philips Research,Stichting LSH-TKI: Topconsortium Kennis en Innovatie - Topsector Life Sciences & Health,TNO

Intervention

Keyword: Oral ecology, Oral Microbiome, Sweeteners

Outcome measures

Primary outcome

The main study parameter is the microbiome composition of dental plaque and

tongue swabs before and after the 2-weeks challenge.

Secondary outcome

The secondary study parameter is the amount of red fluorescent plaque (RFP)

before and after the 2-weeks challenge.

Study description

Background summary

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 a mouth rinse of a carbohydrate sweetener dissolved in water may aid in the treatment of gum disease or periodontal disease.

Study 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 7 times in a period of 5 to 7 weeks including the screening visit. After inclusion, during 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.

Intervention

A mouth rinse containing a sweetener in water 3 times daily after the main meals. The rinse contains a 10% tagatose, trehalose, inulin, palatinose or glucose solution.

Study burden and risks

During the screening visit, people with high caries risk and over 50% inflamed gums will be excluded. The burden consists of 3 times a day rinsing of the oral cavity with 10 mL of fluid (two times 30 seconds rinses) for 2 weeks. The rinse contains a 10% tagatose, trehalose, inulin, palatinose or glucose solution. The sweetener solutions have a pleasant taste. The rinses are used after the 3 main meals. The number of site visits is 7 including the screening. After inclusion before each site visit, the subjects are asked not to clean their teeth 24 h prior to the visit. We also request not to eat or drink 2 h prior to the site visit except for still water. During the visits, plaque samples are collected from the teeth with a plastic dental instrument, a tongue swab is taken which a microbrush, salivary pH is measured outside the oral cavity with a pH-meter after taking two drops of saliva. To minimize the risk of developing oral disease, subjects will rinse for only 2 weeks.

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

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

Exclusion criteria

1. Smokers
2. Overt dental caries
3.DPSI *3+ - 4 (Dutch Periodontal Screening Index)
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
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

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2019
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	30-04-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 23131
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Nederlands Trial Register NL7525
CCMO	NL68654.100.19
OMON	NL-OMON23131