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

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23131

Bron
Nationaal Trial Register

Verkorte titel
PROM

Aandoening

prevention of gingival inflammation and other oral diseases

Ondersteuning

Primaire sponsor: ACTA Dental Research B.V.
Overige ondersteuning: ACTA Dental Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Screening and 5 visits in 14 days

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	04-03-2019
Aantal proefpersonen:	70
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48478
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten