The evaluation of the effects of a prebiotic mouth rinse on the oral ecosystem.

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

Summary

ID

NL-OMON52714

Source
ToetsingOnline

Brief title
The INORE study (INulin and Oral REsilience)

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: Een consortium;via Stichting LSH-TKI,Philips Research

Intervention

Keyword: Experimental gingivitis, Oral ecology, Oral microbiome, Sweeteners

Outcome measures

Primary outcome

The main study parameter is the change in microbial composition (Bray-Curtis similarity) measured from baseline to other study visits, in comparison to the control group.

Secondary outcome

Additionally, changes in microbial diversity (species richness, Shannon diversity index), red fluorescing plaque (RFP) and gingival bleeding on marginal probing (BOMP) will be assessed.

Study description

Background summary

Healthy oral ecosystem is in balance (symbiosis) with the host. It is resilient towards environmental stress and is able to recover from such a stress without collapsing or entering the state of dysbiosis. There is however very little known about the mechanisms involved in maintaining and enhancing this resilience and oral health. Inulin has demonstrated a potential as an oral prebiotic, but its effects on strengthening the oral resilience towards gingivitis (inflammation of gums) are unknown yet.

Study objective

This study aims to evaluate the changes in microbial composition of the oral microbiome (main objective), changes in proportion of the red fluorescing plaque (RFP) and in gingival bleeding on marginal probing (BOMP) (secondary objectives) after exposure to inulin-containing mouth rinse, before, during and after an experimental gingivitis challenge.

Study design

This study is a single-centre, challenge intervention, single-blind, parallel two-groups randomized, placebo-controlled clinical trial.

Intervention

Study subjects will rinse 4 times daily with either 10% inulin solution (test) or 0.5% sodium chloride (salt) solution for 6 weeks. After the first 2 weeks (wash-in period), subjects will abstain from any oral hygiene procedures (experimental gingivitis period) for 2 weeks. The last 2 weeks subjects will continue with normal oral hygiene and a mouth-rinse use (recovery phase).

Study burden and risks

The study will include healthy subjects. During the screening visit, subjects with high caries experience (DMFS>15) and over 50% inflamed gums will be excluded. The subjects will visit ACTA 8 times, including a screening visit, in approximately 8-10 weeks. There will be no invasive procedures performed. Subjects will have to rinse with either the test (10% inulin; an accepted food ingredient) or control (0.5% kitchen salt) solution and will have to abstain from any oral hygiene measures for 14 days. Each visit will last about 30 minutes. There is no direct benefit for the subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

1. Willing and able to give written informed consent and willing and able to comply to all study procedures
2. Mentally-competent and >= 16 years and not above 35 years
3. ASA I, healthy as assessed by a medical questionnaire
4. Non-smoking: definition non-smoker: <1 cigarette every day for at least one year
5. Minimum of 20 natural teeth: at least one un-crowned first or second molar must be present in each quadrant
6. Having visited the dentist for a regular check-up within the last year and having finished the necessary treatment(s)
7. Less than 50% gingival bleeding on probing

Exclusion criteria

1. Not meeting the inclusion criteria
2. ACTA dental student or ACTA employee
3. InHolland oral hygiene student or InHolland employee
4. Participation in a clinical study within the previous 30 days
5. Allergy/intolerance to the ingredients of the test product

General health and use of medication:
6. Smoker
7. Abuse of drugs or alcohol
8. Self-reported pregnancy or breastfeeding
9. Use of antibiotics during the last 3 months
10. Use of anti-inflammatory drugs on a regular basis
11. ASA II or more
12. Prescribed medication (except for contraceptives)

Oral health:
13. Overt dental caries
14. DMFS score > 15
15. Anyone with a dental pocket probing depth >=4-5mm with bleeding on probing plus attachment loss >= 2 mm (Dutch Periodontal Screening Index score 3+/ 4) or a pocket >= 6 mm

16. Clearly inflamed gingiva at the screening, presented as >50% bleeding on probing (BOP)
17. Removable (partial) dentures
18. Removable night guard
19. Oral and/or peri-oral piercings
20. Apparent oral lesions (aphthous ulcers excluded)
21. Presence of orthodontic banding (except for lingual retention wire)
22. Ongoing or planned elective dental treatment involving endodontic treatment and crown and bridge preparation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2022
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO Date:	07-05-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2022

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL72143.018.19