The INORE study (INulin and Oral REsilience)

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23990

Source
Nationaal Trial Register

Brief title
INORE

Health condition

Oral health

Sponsors and support

Primary sponsor: LSH-TKI, ACTA, TNO, Philips, Wrigley
Source(s) of monetary or material Support: LSH-TKI, ACTA, TNO, Philips, Wrigley

Intervention

Outcome measures

Primary outcome

To evaluate the changes in microbial composition of the oral microbiome after two weeks of regular oral hygiene and use of inulin-containing mouth rinse (wash-in phase), followed by two weeks abstaining from any oral hygiene combined with the use of inulin-mouth rinse (experimental gingivitis phase), and the recovery period of two weeks with normal oral hygiene combined with inulin-mouth rinse use (recovery phase) compared to the baseline

and a mouth-rinse containing a placebo rinse.

Secondary outcome

To evaluate the changes 1) in gingival light absorption (GLA), 2) in proportion of the red fluorescing plaque (RFP) and 3) in gingival bleeding on marginal probing (BOMP) after two weeks of regular oral hygiene and use of inulin-containing mouth rinse (wash-in phase), followed by two weeks abstaining from any oral hygiene combined with the use of inulin-mouth rinse (experimental gingivitis phase), and the recovery period of two weeks with normal oral hygiene combined with inulin-mouth rinse use (recovery phase) compared to the baseline and a mouth-rinse containing a placebo rinse.

Study description

Background summary

Rationale: 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.
Objective: to evaluate the changes in microbial composition of the oral microbiome (main objective), in gingival light absorption (GLA), 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.
Study population: Orally and systemically healthy individuals (N=62), aged 16-35.
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).
Main study parameters: 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. Additionally, changes in microbial diversity (species richness, Shannon diversity index), red fluorescing plaque (RFP), gingival light absorption (GLA) and gingival bleeding on marginal probing (BOMP) will be assessed.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

We hypothesize that the exposure to inulin will strengthen the resilience of the oral ecosystem such that 1) it will be able to withstand experimental gingivitis challenge by maintaining a more health-associated microbiome during this challenge and 2) it will enhance the recovery of the ecosystem after the gingivitis challenge.

Study design

Baseline, 2-weeks wash-in period (oral rinse, normal oral hygiene), 2-weeks experimental gingivitis period (oral rinse, no oral hygiene), 2-weeks wash-out period (oral rinse, normal oral hygiene)

Intervention

Four times a day oral rinse with inulin solution or with placebo.

Contacts

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Eligibility criteria

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 16-35 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 (Lie, Timmerman et al. 1998)
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. More than 20% and less than 50% 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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2022
Enrollment:	62
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Coded plaque and tongue samples will be shipped to TNO for sequencing analyses. The obtained coded sequencing data will be shared for subsequent analyses between ACTA, TNO and Philips using secured data transfer protocols.

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8428
Other	METC AMC : METC 2019_808

Study results