

The INORE study (INulin and Oral REsilience)

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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...

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

Samenvatting

ID

NL-OMON23990

Bron

Nationaal Trial Register

Verkorte titel

INORE

Aandoening

Oral health

Ondersteuning

Primaire sponsor: LSH-TKI, ACTA, TNO, Philips, Wrigley

Overige ondersteuning: LSH-TKI, ACTA, TNO, Philips, Wrigley

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

ACTA
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2022
Aantal proefpersonen:	62
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

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.

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8428
Ander register	METC AMC : METC 2019_808

Resultaten