De beoordeling van de effectiviteit van twee probiotica bij het in stand houden van de mondgezondheid: een praktijkonderzoek.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25529

Source
Nationaal Trial Register

Brief title
PrOH-ACT

Health condition

Experimental gingivitis model
Probiotics
Bleeding on marginal probing
Microbiome
Oral health
Probiotica
Mondgezondheid
Tandvleesontsteking

Sponsors and support

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Source(s) of monetary or material Support: Symrise AG
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Intervention

Outcome measures

Primary outcome

Bleeding on marginal probing

Secondary outcome

Microbiome composition

Study description

Background summary

SUMMARY

Rationale: In the current study we will evaluate the effectiveness of two well defined probiotic strains, Lactobacillus paracasei LPc-G110 (CCTCC M 2013691) and Lactobacillus plantarum GOS42 (DSM 32131), in strengthening the oral ecosystem. These strains were selected from a panel of probiotic strains as the first mentioned was most potent in reducing the proportions of several anaerobic genera in ex vivo oral biofilms and the second was very effective in modulating the immune response in a model for gingival immune reactions. After supplementing the oral ecosystem with these probiotics or a placebo for 14 days, we will examine the (strengthened) resilience of the oral ecosystem using a two-week experimental gingivitis model by following the dynamics of clinical, immunological and microbial parameters. After experimental gingivitis, the volunteers will resume their normal oral hygiene routine and stop using the food ingredient. Two weeks later, when the effects of the experimental gingivitis have been reversed, we will examine the oral ecosystem once more to assess to what extent the modulating effects of L. paracasei and L. plantarum on the oral microbiome/ecosystem are still present.

Objective: The primary objective is to evaluate clinically the effectiveness of two oral probiotic strains, compared with a placebo-group, on the gingival health during a two-week

wash-in phase followed by a two-week period refraining from oral hygiene and a two-week wash-out phase. The secondary objective is to explore the dynamics of immunological and microbiological aspects of the oral cavity for the duration of the wash-in phase, the experimental gingivitis phase and the wash-out phase concerning the use of the two oral probiotic strains compared with the placebo-group.

Study design: This study is a single-centre, challenge intervention, double-blind, parallel group (3) randomized, placebo-controlled clinical trial.

Study population: The study population consists of 117 healthy human volunteers of 18 to 55 years old.

Food ingredient and challenge intervention: Subjects are instructed to use one lozenge, 3 times daily after each meal, with the probiotic Lactobacillus plantarum (group A), with the probiotic Lactobacillus paracasei (group B) or lozenges without probiotics (placebo group). The challenge intervention is based on a full mouth experimental gingivitis protocol. For this, subjects will be requested to refrain from any form of oral hygiene for two weeks, resulting in plaque accumulation, temporarily leading to induction of mild gingival inflammation.

Main study parameters: The main study parameter is the status of the gingival health of the participants: bleeding of the gingiva on marginal probing (BOMP). This will be documented to follow the gingival health status before, during and after the intervention and challenge.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks and burden related to this study are judged to be very limited. The time burden per research visit is at most 30 minutes. The induction of mild (short term, temporarily/reversible) gingival inflammation is a well-established method. The mild inflammatory status is completely reversible without long term risk or effects on dental health.
Determination of the clinical parameters are part of standard dental clinical care. In addition, the collection of samples (saliva, plaque) during the study do not require invasive procedures. The probiotic strains, L. paracasei and L. plantarum, are present in various fermented food products and comply with the Qualified Presumption of Safety (QPS) status given by European Food Safety Authority (EFSA). Besides they are both available in many over-the-counter probiotic food ingredients targeted at gut health and oral health.

There is no direct benefit for the participants. The aim of the food ingredients is to sustain oral health in healthy individuals, therefore the effects of these ingredients are examined in an orally and systemically healthy population. As the outcomes of this study could support oral health and prevent oral disease, the very limited burden for the subjects is considered acceptable.

Study objective

To evaluate the effectiveness of two well defined probiotic strains, Lactobacillus paracasei LPc-G110 (CCTCC M 2013691) and Lactobacillus plantarum GOS42 (DSM 32131), in strengthening the oral ecosystem.

Study design

6 visits during 6 weeks

Intervention

3 times daily intake of probiotic lozenges during 4 weeks

two weeks no dental cleaning (brushing)

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. Adult, ≥ 18 years - 55 years;

3. Male and female;

4. Systemically healthy, as assessed by a medical questionnaire (no systemic diseases);

5. Minimum of 20 natural teeth: at least the 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);

Exclusion criteria

1. Not meeting the inclusion criteria;

2. ACTA dental student or ACTA employee;

3. Participation in a clinical study within the previous 30 days;

4. Allergy/Intolerance to the test and placebo products (ingredients) in particular lactose and milk protein content (allergens) in the test products;

General health and use of medication:

5. Smokers, definition non-smoker: <1 cigarette every day for at least one year (e-cigarettes will also be excluded);

6. Abuse of drugs or alcohol;

7. Self-reported pregnancy or breastfeeding;

8. Use of antibiotics during the last 3 months;

9. Need of antibiotic prophylaxis prior to dental treatment;

10. Use of anti-inflammatory drugs on a regular basis;

11. Evidence of any systemic disease or compromised health condition, including:

a. Diabetes mellitus;

b. Bronchitis, tonsillitis or sinusitis;

12. Severe oral- or pharyngeal infections;

13. Current disorders/disease resulting in (self-induced) vomiting;

14. Reduced salivary flow due to pathological reasons (e.g., Sjögren syndrome);

15. Adverse medical history or long-term medication;

16. Prescribed medication (except for contraceptives);

17. Willing not to consume any other probiotic or yoghurt products during the study;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2018
Enrollment:	117
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-04-2018
Application type:	First submission

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	NL6951
NTR-old	NTR7139
Other	CCMO : 65326.048.18

Study results