The effect of glymur rinse on oral microbiological changes and changes in microbial activity related to halitosis

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Determine if the use of Glymur oral rinse for 14 days has an effect on the composition of the oral microbiota. In addition, the effect on total microbial proteolytic activity and oral malodor will be determined.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41897

Source
ToetsingOnline

Brief title
The effect of Glymur rinse on oral microbiological changes

Condition

- Other condition

Synonym
halitosis, oral malodor

Health condition

halitose (slechte adem)

Research involving
Human

Sponsors and support

Primary sponsor: ACTA Dental Research BV (ADR)
Source(s) of monetary or material Support: ADR

Intervention

Keyword: halitosis, microbiological changes, nitrate, oral rinse

Outcome measures

Primary outcome

Change in microbiota from baseline to day 14 and/or to day 31 as determined

with 16S Next Generation Sequencing (NGS) microbiology.

Secondary outcome

Reduction in total protease activity as determined by FRET from:

- saliva

Oral malodor by:

- organoleptic score

Change in Volatile Sulphur Compounds (VSCs) determined by OralChroma®

- breath sample

Extent of tongue coating and tongue body appearance:

- Discoloration

- Thickness

- Tongue body structure and shape

Plaque score determined by the modified Silness & Löe plaque score

Gingival bleeding determined by the bleeding on marginal probing score

Tolerance in test group vs placebo group:

- Mouth feel using a VAS score

Study description

Background summary

An unbalanced oral microbial ecology can lead to several types of pathology and discomfort. These are usually tackled by the use of an anti-microbial mouthwash. These unspecific mouthwashes actually only reduce the total microbial load and do not re-establish microbial balance. In the current pilot trial an alternative approach will we evaluated where instead of killing all microbes, specifically beneficial microbes will be stimulated. The imbalanced oral ecology that will be tackled is the one that leads to the discomfort of oral malodour (or the condition termed halitosis). Here strictly anaerobic microorganisms that via proteolytic activity produce (smelly) volatile sulphur compounds dominate oral microbial ecology. The hypothesis is that by using a mouth rinse that contains nitrate (BM500), conditions are changed in such a way that they favour nitrate-reducing microorganisms (firmly established as beneficial oral bacteria) and hence re-establishment of an ecological balance. As a result (i) proteolytic microorganisms will be outcompeted and (ii) production of smelly products will be reduced.

Study objective

Determine if the use of Glymur oral rinse for 14 days has an effect on the composition of the oral microbiota. In addition, the effect on total microbial proteolytic activity and oral malodor will be determined.

Study design

Single centre, placebo controlled, double-blind exploratory pilot study in 2 groups of 10 systemically healthy volunteers.

Intervention

One group of 10 volunteers will rinse with Glymur (2x10 mL for 30 seconds) 3 times a day for a duration of 14 days and the other group of 10 volunteers will rinse with placebo (2x10 mL for 30 seconds) 3 times a day for a duration of 14 days.

Study burden and risks

The risks for this study are negligible as the Glymur rinse contains components that are known to be non-hazardous/safe. In addition, the product will only be used to rinse very shortly and therefore it is anticipated that there will not be an actual uptake of any components.
The burden for the volunteers that participate in the study is minimal. They will make 6 short visits to the site and the data for this study will be obtained by non-invasive samples of the mouth (saliva, tongue and interproximal plaque). The benefit for the volunteers will be the possible relieve of halitosis discomfort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age: >= 18 years - 55 year
- Male and female
- Classified as systemically healthy, assessed by medical questionnaire
- Organoleptic score of >= 2
- Presence of Volatile Sulphur Compounds (VSC*s) using Oral Chroma®
- Minimum of 20 natural teeth: all first molars and second (or third molars) in the upper jaw available
- Agree to present with *overnight* plaque
- Agree to present without eating and drinking 2 hours prior to visit
- Having visited the dentist for a regular check-up within the last year and having finished the necessary treatment.
- Willing and able to give written informed consent
- Willing to consent to use their collected anonymous and coded body materials for further research.

Exclusion criteria

- Anyone presenting with a probing depth >= 5mm with bleeding on probing and attachment loss >= 2 mm, Dutch Periodontal Screening Index score 3+/ 4
- Overt dental caries
- Interproximal restorations between all molars
- Smokers, definition non-smoker: <1 cigarette every day for at least one year
- Removable partial dentures
- Removable night guard
- Oral and/or peri-oral piercings
- Apparent oral lesions (aphthous ulcers excluded)
- Presence of orthodontic banding (except for lingual retention wire)
- Abuse of drugs/ alcohol
- ACTA dental student or ACTA professional
- Participation in a clinical study within the previous 30 days

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2015
Application type:	First submission
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	NL49303.029.15