The effect of S. persica roots on the microbial viability in plaque and saliva and on the microbial composition of plaque

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To get insight in the effect of S. persica roots on the viability and bacterial composition of dental plaque and saliva

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38758

Source
ToetsingOnline

Brief title
Effects of S. persica roots on plaque and saliva

Condition

- Other condition

Synonym
Microflora saliva and dentalplaque/biofilm

Health condition

microflora van speeksel en tandplaque

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Oral microflora, S. persica, Substantivity, Viability

Outcome measures

Primary outcome

The primary study parameter is the percenatge live and dead bacteria in plaque

and saliva and the similarity (%) between the composition of the oral

microflora of the plaque samples before and after the use of S. persica root.

Secondary outcome

Not applicable

Study description

Background summary

Over the years, many antimicrobial substances for oral hygiene have appeared on the market. Aside from mouthrinses with antimicrobial claims, toothpastes have also added active ingredients helping with plaque control and holding antibacterial claims. Besides chemical synthetic additives (like chlorhexidine), herbal sources for antimicrobial substances have also been approached. One particularly popular extract in the Middle East is that of the root of the Salvadora persica (S. persica) tree also called the "miswak" or "siwak". In vitro, the S. persica root showed a strong growth inhibitory effect on Aggregatibacter actinomicetemcomitans, Porphyromonas gingivalis and Streptococcus mutans. In general it is suggested that gramnegative bacteria are more susceptible for S. persica roots. However nothing is known about the effect of S. persica roots on the viability of plaque bacteria.
Another very important characteristic of antimicrobials is that they can adhere to soft and hard tissues and dental plaque in the oral cavity for some time. Subsequently they start releasing to saliva and dental plaque and therewith extend there action for a longer time, which is called substantivity. Regarding

S. persica and substantivity no data are available.

Study objective

To get insight in the effect of S. persica roots on the viability and bacterial composition of dental plaque and saliva

Study design

Single armed comparative trial

Study burden and risks

The burden for the volunteers is that they cannot brush their teeth early in the morning on the survey day, during the study period they need to chew S. persica root three times a day for 1 min. There are no predictable risks in this study.

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

Volunteers are recruited at the Dentistry and Oral Hygiene academy, University Medical Center Groningen, University of Groningen.
- Minimal 5 natural permanent teeth per quadrant present.
- Good health of the subjects

Exclusion criteria

Recent use of antibiotics (3 months) prior to the start of the study
Recent use of mouth rinses and/or S. persica oral hygiene products (1 month) prior to the start of the study
Smokers

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2014
Enrollment:	15

Type:	Actual

Ethics review

Approved WMO Date:	26-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL44287.042.13