The effect of maltitol sweetened chewing gum on the oral microbiology -RCT-

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27321

Source
NTR

Brief title
Bart Keijser Roquette (BAKER)

Health condition

1. Composition of the supragingival plaque microbiome

2. Gingivitis

3. Caries

Sponsors and support

Primary sponsor: ACTA: Dental Research B.V.
Source(s) of monetary or material Support: TNO- Earth Environment and Life Sciences

Intervention

Outcome measures

Primary outcome

2 Supragingivale tandplaque samples

Secondary outcome

1. Gingivitis

2. Caries

3. Gingival biotype

4. Food Frequency Questionnaire

Study description

Background summary

This metgenomic study is based on the Marsh¡¯s theory (Marsh et al 2006, BMC oral health). This theory consist in considering that the bacteria of dental plaque belong to a dynamic equilibrium where various factors can be deleterious. Indeed environment(diet health status) can let or not some pathogenic bacteria colonizing dental plaque. The equilibrium can move form a ¡¯¡¯healthy state¡¯¡¯ to a ¡¯¡¯sick state¡¯¡¯. Sugar alcohols, a class of polyols, are commonly added to foods because of their lower calorific content compared to sugars. Maltitol, sorbitol, xylitol, erythritol are often used as sweetner in chewing gum because they are not broken down by bacteria in the mouth or metabolized to acids, and thus do not contribute to tooth decay. Importantly, polyol sugars promote tooth mineralization by increasing the flow of saliva. Xylitol and sorbitol have been demonstrated in vivo and in vitro to inhibit growth of a number of cariogenic bacterial species, including mutans streptococci, most prominently Streptococcus mutans and Streptococcus sobrinus. The exact mechanism of action of xylitol on mutans streptococci (MS) is not fully known but habitual xylitol consumption, at high enough doses reduces counts of MS, apparently making plaque and mutans streptococci less adhesive to teeth. Loesche et al showed that consumption of 5−7 g of xylitol in chewing gum reduced MS in both plaque and saliva but not counts of S. sanguis. Very little is actually known about the effects of the polyole sugars on the oral microbiota. This study aims to establish the effects of frequent consumption of chewing gum (sweetened with maltitol or the use of gum base) during 28 days on the oral microbiome composition, and to relate to effects to microbial risk factors for gingivitis and caries. Also, the prolonged effects of chewing gum (sweetened with maltitol or the use of gum base) consumtion are examined after 2 weeks. The study can contribute to effective dosage of gum consumption and improve our understanding on the level of the dental plaque ecosystem.

Study objective

What is the effect of the use of a maltitol sweetened chewing gum compared to a gum base and no gum in during a 28 days on the composition of the supragingival plaque microbiome in healthy non dental students ≥ 18 years old.

Study design

Screening

Visit 1: baseline

Visit 2: day 28

Visit 3: day 42

Intervention

Intervention: maltitol sweetened chewing gum
Placebo: gum base
Control: no gum

Contacts

Public
Acedemisch Centrum Tandheelkunde Amsterdam (ACTA)
Afdeling CPT- Parodontologie
Gustav Mahlerlaan 3004
G.A. Weijden, van der

Amsterdam 1081 LA
The Netherlands
+31 (0)20 5188307
Scientific
Acedemisch Centrum Tandheelkunde Amsterdam (ACTA)
Afdeling CPT- Parodontologie
Gustav Mahlerlaan 3004
G.A. Weijden, van der

Amsterdam 1081 LA
The Netherlands
+31 (0)20 5188307

Eligibility criteria

Inclusion criteria

1. Male and female Students age ≥18 years (upper limit 45 years old)

2. Classified as systemically healthy, assessed by medical questionnaire

3. Non-smokers (Lie et al. 1998) definition non-smoker: <1 cigarette every day for at least one year

4. Minimum of 20 natural teeth: at least 5 evaluable teeth in each quadrant DPSI 0-3-

5. With moderate gingivitis (30-60% BOMP) (Keukenmeester et al.2013 submitted).

6. No partial dentures

7. No orthodontic banding

8. No oral lesions Subjects who do not use an interdental cleaning device at home.

Exclusion criteria

1. Anyone presenting with a probing depth ¡Ý5mm with bleeding on probing and attachment loss ≥ 2 mm

2. Overt dental caries

3.Usage of any interdental device as part of regular daily oral care Smokers DPSI ≥3+-4 (appendix 13.4)

4. Removable (partial) dentures Crowns, bridges and implant supported restorations

5. Removable night guard

6. Oral and/or peri-oral piercings

7. Apparent oral lesions (aphthous ulcers excluded)

8. Presence of orthodontic banding (except for lingual retention wire)

9. Dental student or dental professional

10. Participation in a clinical study within the previous 30 days

11. A big chewing-gum consumer > 3 gums a day

General health and use of medication:

1. Self-reported pregnancy or breastfeeding
2. Use of antibiotics during the last 2 months
3. Need of antibiotic prophylaxis prior to dental treatment Use of anti-inflammatory drugs on a regular basis Evidence of any systemic disease or compromised health condition

4. Adverse medical history or long-term medication Prescribed medication (except for anti-contraceptives - birth control pills)

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):	10-09-2013
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-09-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38887
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3993
NTR-old	NTR4165
CCMO	NL45518.018.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38887

Study results

Summary results
N/A