Evaluation of a dentifrice with natural ingredients in the prevention of plaque and gingivitis

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19874

Source
Nationaal Trial Register

Brief title
N/A

Health condition

gingivitis

Sponsors and support

Primary sponsor: GABA International AG
Emil Frey-Strasse 100
CH-4142 M¨¹nchenstein
Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

BLEEDING ON MARGINAL PROBING (BOMP) ¨C Angular Bleeding Index (Van der Weijden

1994).

This score will be scored on the pre-experimental phase, baseline and at the final examination (after 4 months)

The gingiva is lightly dried with compressed air and lightly probed with a probe. The probe is inserted into the gingival crevice to a depth of approximately 2mm or until slight resistance is felt. The probe is run gently along the marginal gingival holding the probe at a an angle of approximately 60 degrees to the longitudinal axis of the tooth and in contact with the sulcular epithelium. Minimum axial force is used to avoid undue penetration in the tissue. The probe is moved around the crevice gently stretching the epithelium. A bleeding score is given to six gingival areas of the tooth. These are the disto-vestibular, vestibular, mesio-vestibular, disto-lingual, lingual and the mesio-lingual regions.

Secondary outcome

MODIFIED GINGIVAL INDEX visual aspect only; Lobene et al. 1986)

This score will be scored on the pre-experimental phase, baseline and at the final examination (after 4 months)

The gingival condition is assessed using visual signs of inflammation as scored according to the criteria of the Modified Gingival Index on a scale of 0-4 (0=pale pink, 4= reddish blue enlarged) and by bleeding on marginal probing (BOMP), where the gingival margin is probed at an angle of approximately 60 degree to the longitudinal axis of the tooth and the absence or presence of bleeding is scored within 30 seconds of probing on a scale 0-2 (0=non-bleeding, 1= pinprick bleeding, 2=excess bleeding).

PLAQUE (Quigley & Hein, 1962)

This score will be scored on the pre-experimental phase, baseline and at the final examination (after 4 months)

Plaque is assessed after disclosing with Mira-2-Ton® (Hager & Werken GmbH & Co. KG. Duisburg, Germany), using the Turesky (Turesky et al.1970) modification of the index (Quigley & Hein 1962) scored at six sites per tooth as suggested by Lobene et al. (1982) where the absence or presence of plaque is recorded on a scale 0-5 (0=no plaque, 5=plaque covered more than two-thirds of the tooth surface).

Study description

Background summary

The study is designed to evaluate the effect of a dentifrice with natural ingredients over a period of 4 months. 90 subjects (non-dental) will be selected on the basis of having moderate gingival inflammation. The single blind study consists of 2 phases: a pre-experimental phase of 3 weeks and an experimental period of 4 months. At the start of the pre-experimental phase gingivitis (MGI) bleeding upon marginal probing (BOMP) and plaque (Quigley & Hein) will be assessed. Subjects receive a written instruction in the use of a manual toothbrush. Furthermore, a combination of Bocasan® and chlorhexidine 0.20% will be used to rinse 2 times per day during the 3 weeks prior to the second fase of the experiment. The baseline assessment is scheduled 3 weeks later. Subjects are randomly assigned to one of 2 groups (test & control). All will be instructed to brush their teeth with their assigned toothpaste for 2 minutes 2 times a day using the timer. Clinical examinations will be performed after 4 months. All parameters assessed at the start of the study are evaluated after 4 months.

Study objective

The dentifrice with natural ingredients (Verum) inhibit 10% less gingivitis compared to the placebo dentifrice over a period of 4 months in healthy subjects.

Study design

-Pre-experimental phase (3 weeks)

-Experimental phase

-baseline

-4 months

Intervention

Pre-experimental phase (3 weeks):

Brushing 2x a day:-Everclean toothpaste (a standard toothpaste)and -Aronal oko-dent toothbrush.

Rinsing 2x a day: - 0,2% Chloorhexidine mouthrinse (Corsodyl®) and 10 ml waterperoxide-oplossing (Bocasan®)

Experimental phase (4 months):

Brushing 2x a day:-Verum toothpaste(TEST OR CONTROL) in combination with the Aronal

oko-dent toothbrush

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

Inclusion:

1. At least 5 evaluable teeth in each quadrant

2. Moderate gingivitis (¡Ý40% bleeding on marginal probing)

Exclusion criteria

Exclusion:

1. Orthodontic banding or wires or partial dentures

2. Oral laesions or periodontol pockets¡Ý 5mm

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2008
Enrollment:	90
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1170
NTR-old	NTR1215
Other	MEC : MEC 07/021
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A