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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19874

Bron
NTR

Verkorte titel
N/A

Aandoening

gingivitis

Ondersteuning

Primaire sponsor: GABA International AG
Emil Frey-Strasse 100
CH-4142 M¨¹nchenstein
Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

-Pre-experimental phase (3 weeks)

-Experimental phase

-baseline

-4 months

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion:

1. At least 5 evaluable teeth in each quadrant

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion:

1. Orthodontic banding or wires or partial dentures

2. Oral laesions or periodontol pockets¡Ý 5mm

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-02-2008
Aantal proefpersonen:	90

Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1170
NTR-old	NTR1215
Ander register	MEC : MEC 07/021
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A