The plaque inhibitory effect of a CPC mouthrinse in a 3-day plaque accumulation model-A cross-over study

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The CPC-mouthrinse inhibit 15% less of 'de novo' plaqueformation compared to a placebo and hexitine over a period of 3 days in a non-brushing model.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25347

Bron
NTR

Verkorte titel
N/A

Aandoening

Gingivitis

Ondersteuning

Primaire sponsor: Dentaid International
Overige ondersteuning: Dentaid International

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Bleeding on Marginal Probing (BOMP) – Angular Bleeding Index (Van der Weijden 1994).

This score will be done at session 1, 2 and 3.

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 present study aims at testing whether a CPC-mouthrinse has a potential to inhibit ‘de novo’ plaque formation as compared to a placebo and hexetidine.

Doel van het onderzoek

The CPC-mouthrinse inhibit 15% less of 'de novo' plaqueformation compared to a placebo and hexitine over a period of 3 days in a non-brushing model.

Onderzoeksopzet

Session 1:

-Professional oral profylaxis

-Measurements (after 3 days of profylaxis)

Session 2:

-Professional oral profylaxis

-Measurements (after 3 days of profylaxis)

Session 3:

-Professional oral profylaxis

-Measurements (after 3 days of profylaxis)

Onderzoeksproduct en/of interventie

At session 1:

Subjects have to rinse 3 times a day during 3 days with CPC-mouthrinse, Hexitine mouthrinse or a placebo mouthrinse.

The above mentioned procedure will be repeated also at session 2 and 3 in order to have all subjects run the protocol with all three products.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Be between the ages of 18 and 70

2. Be in good general health as determined by the investigator/designee based on a review of the medical history/update

3. Possess at least 5 evaluable teeth in each quadrant in the lower jaw

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Orthodontic banding or wires or partial dentures

2. Severe periodontal disease (no sites with PPD > 5mm), including but not limited to purulent exudate, generalized mobility, and or severe recession

3. Any disease or conditions that could be expected to interfere with examination procedures or the subject safely completing the trial.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	27-05-2008
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	03-06-2008
Soort:	Eerste indiening

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	NL1283
NTR-old	NTR1329
Ander register	: MEC 08/112
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A