A 6-month placebo-controlled CPC-mouthrinse study.

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The present study aims at testing whether the 0.07% CPC-mouthrinse has a potential to inhibit gingival inflammation as compared to a placebo over a 6 month period.

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

Samenvatting

ID

NL-OMON25365

Bron
Nationaal Trial Register

Aandoening

Gingivitis

Ondersteuning

Primaire sponsor: Dentaid International, Ronda Can Fatjo 10, 08290 CERDANYOLA - BACELONA, SPAIN, masdevall@dentaid.es
Overige ondersteuning: Dentaid International, Ronda Can Fatjo 10, 08290 CERDANYOLA - BACELONA, SPAIN, masdevall@dentaid.es

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
Maintaining an adequate low level of plaque through daily tooth brushing is often not feasible. Chemotherapeutic agents as an adjunct to mechanical plaque control would be valuable. Cetylpyridinium chloride (CPC) has proven to be an effective inhibitor of plaque accumulation.

Objective of the study:
The present study aims at testing whether the 0.07% CPC-mouthrinse has a potential to inhibit gingival inflammation as compared to a placebo over a 6 month period.

Study design:
This study is designed as a double examiner-blind, 2-group cross-over. Subjects will recruited in The Netherlands and receive a unique trial number and will be randomly assigned to one of the 2 groups according to a Latin square design. On the 1st appointment microbiologic measurements (plaque- and saliva samples) and clinical parameters (plaque, bleeding on marginal probing, and stain) will be scored. After completion of the clinical assessments a dental hygienist will provide a professional dental scale and polish. Each subject will receive a written and verbal instruction about how to use the mouthrinse. The subjects will also receive a standard toothbrush and toothpaste to brush 3 times a day. All subjects are instructed to use their allocated products 3 times a day. At this moment subjects will rinse for the first time with their allocated mouthrinse. After 3 and 6 months, subjects return to the clinic for the microbiological and clinical assessments. Subsequently all subjects receive a questionnaire to evaluate their attitude towards the used products using Visual Analogue Scales (VAS-scores).

Doel van het onderzoek

The present study aims at testing whether the 0.07% CPC-mouthrinse has a potential to inhibit gingival inflammation as compared to a placebo over a 6 month period.

Onderzoeksopzet

Baseline, 3 months and 6 months.

Onderzoeksproduct en/of interventie

At baseline, 3 months and 6 months:

1. Brushing 2x a day: Everclean toothpaste (a standard toothpaste) and VITIS Encias toothbrush;

2. Rinsing 3x a day for 30 seconds with 15 ml with 0.07% CPC-mouthrinse OR a placebo mouthrinse.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. >18 years of age;

2. A minimum of 5 evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Oral lesions and/or periodontal pockets >5 mm;

2. Pregnancy or systemic diseases such as diabetes.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-06-2009
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-06-2009

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	NL1745
NTR-old	NTR1855
Ander register	Academisch medisch centrum : 09/098
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A