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

No registrations found.

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

Summary

ID

NL-OMON25365

Source
Nationaal Trial Register

Health condition

Gingivitis

Sponsors and support

Primary sponsor: Dentaid International, Ronda Can Fatjo 10, 08290 CERDANYOLA - BACELONA, SPAIN, masdevall@dentaid.es
Source(s) of monetary or material Support: Dentaid International, Ronda Can Fatjo 10, 08290 CERDANYOLA - BACELONA, SPAIN, masdevall@dentaid.es

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

1. BLEEDING ON MARGINAL PROBING (BOMP, 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;

2. GRÜNDEMANN MODIFIED STAIN INDEX (GMSI, Grundemann 2000).
The buccal surface is divided into four zones, by straightening the angle of the mesial and distal surfaces to allow for a wider gingival/marginal area. In this study, the buccal surfaces of all scorable teeth will be scored on a scale 0-3. (0= no stain, 3= heavy stain);

3. VAS-QUESTIONAIRE.
Results from the VAS questionnaire to evaluate the subject¡¯s attitude towards to the used products.

Study description

Background summary

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).

Study objective

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

Baseline, 3 months and 6 months.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. >18 years of age;

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

Exclusion criteria

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

2. Pregnancy or systemic diseases such as diabetes.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-06-2009
Application type:	First submission

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

Study results

Summary results

N/A