Prevention of Plaque formation and Gingivitis:
A 6-month placebo-controlled CPC-mouthrinse study

Published: 16-09-2009
Last updated: 04-05-2024

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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33187

Source
ToetsingOnline

Brief title
Plaque and Gingivitis: 6 months CPC-mouthrinse

Condition

- Other condition

Synonym
inflammation of the gingiva

Health condition

gingivitis

Research involving
Human

Sponsors and support

Primary sponsor: ACTA Dental Research B.V.
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: Cetylpyridinium chloride, Gingivitis, Mouthrinse, Plaque

Outcome measures

Primary outcome

Quigley & Hein plaque index

Secondary outcome

Bleeding on marginal probing index, Staining index and VAS-questionnaire

Study description

Background summary

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.

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

This study is designed as a double examiner-blind, 2-group cross-over. Subjects will 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 plaque accumulation, gingivitis and staining 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 clinical assessments. Subsequently all subjects receive a questionnaire to evaluate their attitude towards the used products using Visual Analogue Scales (VAS-scores).

Intervention

During 6 months subjects have to rinse 3 a day with CPC-mouthrinse or a placebo mouthrinse.

Study burden and risks

No

Contacts

Public
ACTA Dental Research B.V.

Louwesweg 1
1066 EA AMSTERDAM
NEDERLAND
Scientific
ACTA Dental Research B.V.

Louwesweg 1
1066 EA AMSTERDAM
NEDERLAND

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

-*18 years of age, -a minimum of 5 evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires)

Exclusion criteria

-oral lesions and/or periodontal pockets >5 mm - 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
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-06-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL27846.018.09