The effect of application of 0.12% chlorhexidine gel-toothpaste compared to 0.12% chlorhexidine mouthwash and regular toothpaste in a 3 day non-brushing model on plaque accumulation.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20736

Source
Nationaal Trial Register

Brief title
DAGMAR Daily Application of a Gingival Maintenance Antimicrobial Regimen

Health condition

Dental plaque.

Sponsors and support

Primary sponsor: The study is only sponsored by providing study products
Dentaid Benelux, Houten, the Netherlands: Perioaid 0.12% chlorhexidine gel-toothpaste, Perioaid 0.12% chlorhexidine mouthwash and regular toothpaste.
Hogeschool INHOLLAND, school of health te Diemen, the Netherlands: Gift vouchers.

Intervention

Outcome measures

Primary outcome

Quigley & Hein plaque-index after 3 days (72 hours) of ¡®de novo¡¯ plaque accumulation.

Secondary outcome

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

Study description

Background summary

Background:

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. Chlorhexidine has proven to be an effective inhibitor of plaque accumulation. Lower concentrations of chlorhexidine might decrease the chances for adverse effects.

Aim:

The purpose of the study is to assess the effect of tray application of 0.12% chlorhexidine gel-toothpaste on ¡®de novo¡¯ plaque accumulation compared to the effect of rinsing with 0.12% chlorhexidine mouthwash and tray application of a regular toothpaste in a 3 day non-brushing model.

Material and methods:

The study is designed as a single blind, randomized 3-arm parallel clinical trial. During a 3 day non brushing period, one group will use gel twice daily applied with a fluoride tray. This gel contains 0.12% chlorhexidine. One group will use a regular toothpaste twice daily also applied with a fluoride tray. One group will use 0.12% chlorhexidine mouthwash, rinsing twice daily with 15 ml. 3 Days later all subject will return. After disclosing, plaque accumulation is scored. Subsequently all subjects receive a questionnaire to evaluate their attitude towards the used products using Visual Analogue Scales (VAS-scores). After the experimental period, habitual oral hygiene procedures may be resumed.

Population:

90 Subjects, >18 years, systemically healthy, with at least 5 teeth per quadrant and no pockets >5 mm, no orthodontic appliance or removable (partial) denture

Intervention:

Tray application of 0.12% chlorhexidine gel-toothpaste twice daily during 2 minutes or tray application of regular toothpaste twice daily during 2 minutes or tray or rinsing with 0.12% chlorhexidine mouthwash twice daily during 1 minute, during a 3 days non-brushing period.

Time load for subjects:

Maximum 4 minutes of product uses per day during 3 days and a total of 40 minutes professional prophylaxis and clinical assessment.

Risk for subjects:

None.

Endpoint:

Quigley & Hein plaque index assessed after 3 days of ¡®de novo¡¯ plaque accumulation.

Study objective

Tray application of 0.12% chlorhexidine gel-toothpaste has more than 15% better effect on ¡®de novo¡¯ plaque accumulation compared to tray application of regular toothpaste in a 3 day non-brushing model.

Study design

N/A

Intervention

Tray application of 0.12% chlorhexidine gel-toothpaste twice daily during 2 minutes or tray application of regular toothpaste twice daily during 2 minutes or rinsing with 0.12% chlorhexidine mouthwash twice daily during 1 minute, during a 3 day non-brushing period.

Contacts

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Eligibility criteria

Inclusion criteria

1. > 18 years;

2. Systemically healthy;

3. >= 20 teeth;

4. 5 teeth per kwadrant;

5. No pockets >5 mm;

6. No orthodontic appliances;

7. No removable (partial) dentures.

Exclusion criteria

1. Use of medication possibly influencing normal gingival health;

2. Pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2005
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	14-09-2005
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	NL236
NTR-old	NTR274
Other	: N/A
ISRCTN	ISRCTN57974544

Study results

Summary results

1. Int J Dent Hyg. 2007 Feb;5(1):45-52.
2. J Periodontol. 2008 Aug;79(8):1395-400.