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.

Gepubliceerd: 14-09-2005 Laatst bijgewerkt: 13-12-2022

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.

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

Samenvatting

ID

NL-OMON20736

Bron
Nationaal Trial Register

Verkorte titel
DAGMAR Daily Application of a Gingival Maintenance Antimicrobial Regimen

Aandoening

Dental plaque.

Ondersteuning

Primaire 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of medication possibly influencing normal gingival health;

2. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	19-09-2005
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-09-2005
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	NL236
NTR-old	NTR274
Ander register	: N/A
ISRCTN	ISRCTN57974544

Resultaten

Samenvatting resultaten

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