The effect of 1% chlorhexidine gel compared to 0.12% chlorhexidine gel-toothpaste or 0.2% chlorhexidine mouthwash or regular toothpaste in a 3 day non-brushing model on plaque accumulation.

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Tray application of 1% chlorhexidine gel has more than 15% better effect on de novo plaque accumulation compared to tray application of regular toothpaste or 0.12% chlorhexidine gel-toothpaste in a 3 day non-brushing model.

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

Samenvatting

ID

NL-OMON23121

Bron
Nationaal Trial Register

Verkorte titel
DAGMAR 2 Daily Application of a Gingival Maintenance Antimicrobial Regimen 2

Aandoening

Dental plaque, bleeding on probing

Ondersteuning

Primaire sponsor: Academic Center Dentistry Amsterdam (ACTA)
Overige ondersteuning: Dentaid Benelux, GlaxoSmithKline Utrecht

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 1% chlorhexidine gel on de novo plaque accumulation compared to the effect of 0.12% chlorhexidine gel- toothpaste or a regular toothpaste tray application or rinsing with 0.2% cholhexidine mouthwash in a 3 day non-brushing model.

Material and methods:

The study is designed as a single blind, randomized 4-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 1% chlorhexidine. One group will use 0.12% chlorhexidine gel-toothpaste and one group a regular toothpaste twice daily also applied with a fluoride tray. One group will use 0.2% chlorhexidine mouthwash, rinsing twice daily with 10 ml. 3 Days later all subjects will return. After disclosing, plaque accumulation is scored. Also the bleeding on marginal probing is done. 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:

120 Subjects, ¡Ý18 years, systemically healthy, with at least 5 teeth per quadrant and no pockets ¡Ý5 mm, no orthodontic appliance or removable (partial) denture.

Intervention:

Tray application of 1% chlorhexidine gel or 0.12% chlorhexidine gel-toothpaste or regular toothpaste twice daily during 2 minutes or rinsing with 0.2% 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 1% chlorhexidine gel has more than 15% better effect on de novo plaque accumulation compared to tray application of regular toothpaste or 0.12% chlorhexidine gel-toothpaste in a 3 day non-brushing model.

Onderzoeksopzet

-Professional oral profylaxis;

-Measurements (3 days after profylaxis).

Onderzoeksproduct en/of interventie

Tray application of 1% chlorhexidine gel or 0.12% chlorhexidine gel-toothpaste or regular toothpaste twice daily during 2 minutes or rinsing with 0.2% chlorhexidine mouthwash twice daily during 1 minute, during a 3 day non-brushing period.

Contactpersonen

Publiek

Hogeschool INHOLLAND,
School of Health,
Postvak 32,
Louwesweg 1
D.E. Slot
Louwesweg 1
Amsterdam 1066 EA
The Netherlands
+31 (0)20 5188402

Wetenschappelijk

Hogeschool INHOLLAND,
School of Health,
Postvak 32,
Louwesweg 1
D.E. Slot
Louwesweg 1
Amsterdam 1066 EA
The Netherlands
+31 (0)20 5188402

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. >= 18 years

2. Systemically healthy

3. >= 20 teeth

4. at least 5 teeth per quadrant

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:	11-09-2007
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-09-2008
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	NL1369
NTR-old	NTR1429
Ander register	MEC AMC : 07/152
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A