

Preventive strategies in order to obtain healthy teeth for life.

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The present study aims at testing whether the positive effect of rinsing 3 weeks with a combination of chlorhexidine and sodiumperoxyborate will last up to 9 months and possibly up to 12 months. This concept placed in a future prospective could...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29095

Bron

NTR

Verkorte titel

HT4L

Aandoening

Gingivitis

Ondersteuning

Primaire sponsor: ACTA-ADR

Overige ondersteuning: Financial support:
ZonMw

Material support:

GSK, Utrecht, The Netherlands

Oral-B, Rotterdam, The Netherlands

Sara Lee, Amersfoort, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

BLEEDING ON MARGINAL PROBING (BOMP, Van der Weijden 1994). This score will be baseline, 3 weeks, 3, 6, 9 and 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

It is generally accepted that bacterial plaque is an important etiological factor of periodontal disease. Mechanical plaque removal is the primary method for controlling supra-gingival plaque. Patients' efforts are however often compromised by the presence of hard-to-reach areas as well as inadequate skill, poor motivation and lack of compliance. Consequently above the age of 35 almost everybody has inflamed periodontal tissues. Antimicrobial mouthrinses as adjuncts to mechanical oral hygiene regimens have been introduced as a means to enhance plaque removal. In 2 recent studies a stringent protocol of 1 oral hygiene instruction, 1 session of professional and 3 weeks of rinsing with chlorhexidine and sodiumperoxyborate significantly improved the level of gingival health which was maintained up to a subsequent period of 9 months. The design of the present study is based on a model as previously published by Svatun et al. (Svatun et al. 1987, Svatun et al. 1989) and will test the concept that good gingival health can be maintained by the use of a prophylactic aid.

Objective:

The objective of the study is to evaluate the long-term effect of a short preventive intervention on oral health.

Study design:

240 subjects will be divided in 6 randomised groups. All 6 groups will perform a basic regime of 2x daily brushing with a standard toothbrush and toothpaste. Group 1 and 2 will brush only, group 3 will receive additionally 1 oral hygiene instruction, group 4 will receive 1 professional prophylaxis, group 5 will rinse for 3 weeks with chlorhexidine and sodiumperoxyborate and group 6 will receive all 3 supplementary preventive interventions.

Doel van het onderzoek

The present study aims at testing whether the positive effect of rinsing 3 weeks with a combination of chlorhexidine and sodiumperoxyborate will last up to 9 months and possibly

up to 12 months. This concept placed in a future prospective could lead to a preventive strategy whereby people can rinse every year for 3 weeks with chlorhexidine and sodium-peroxyborate and improve the oral health for the year to come. In turn it is beneficial to the patient's general health and quality of life and will reduce the costs of dentistry for the society.

Onderzoeksopzet

1. Group 1: baseline, 3 weeks and 12 months;
2. Group 2-6: baseline, 3 weeks, 3, 6, 9 and 12 months.

Onderzoeksproduct en/of interventie

A basic regime of 2x daily brushing with a standard toothbrush and toothpaste.

1. Group 1 + 2: with no additional regimen;
2. Group 3: with additionally 1 professional oral hygiene instruction;
3. Group 4: with additional 1 professional prophylaxis;
4. Group 5: with additional rinsing for 3 weeks with chlorhexidine and sodiumperoxyborate;
5. Group 6: with additional a combination of 1 professional oral hygiene instruction, 1 professional prophylaxis and for 3 weeks rinsing with chlorhexidine and sodiumperoxyborate.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18 years of age or older;
2. A minimum of 5 evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires);
3. 40% bleeding on marginal probing or more.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Oral lesions and/or periodontal pockets >5 mm;
2. Pregnancy;
3. Systemic diseases such as diabetes.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-11-2009
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	13-10-2009
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	NL1936
NTR-old	NTR2053
Ander register	MEC : 09/195
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A