Preventive strategies in order to obtain healthy teeth for life.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29095

Source
NTR

Brief title
HT4L

Health condition

Gingivitis

Sponsors and support

Primary sponsor: ACTA-ADR
Source(s) of monetary or material Support: Financial support:
ZonMw

Material support:
GSK, Utrecht, The Netherlands
Oral-B, Rotterdam, The Netherlands
Sara Lee, Amersfoort, The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. PLAQUE (Quigley & Hein, 1962) This score will be scored baseline, 3 weeks, 3, 6, 9 and 12 months;

2. STAINING (Grundemann GMSI, 2000) This score will be scored at baseline, 3 weeks, 3, 6, 9 and 12 months.

Study description

Background summary

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 ¡n 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.

Study objective

The present study aims at testing whether the positive effect of rinsing 3 weeks with a combination of chloorhexidine 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.

Study design

1. Group 1: baseline, 3 weeks and 12 months;

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Oral lesions and/or periodontal pockets >5 mm;

2. Pregnancy;

3. Systemic diseases such as diabetes.

Study design

Design

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

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-11-2009
Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-10-2009
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	NL1936
NTR-old	NTR2053
Other	MEC : 09/195
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A