

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

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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%...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31135

Source

ToetsingOnline

Brief title

Effect of 1% chlorhexidine gel on plaque accumulation

Condition

- Other condition

Synonym

inflammation of the gingiva

Health condition

gingivitis

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chlorhexidine, chlorhexidine mouthwash, chlorhexidine-gel, plaque

Outcome measures

Primary outcome

Quigley & Hein plaque index assessed after 3 days of *de novo* plaque accumulation.

Secondary outcome

Bleeding on marginal probing index and VAS-questionnaire

Study description

Background summary

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.

Study objective

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% chlorhexidine mouthwash in a 3 day non-brushing model.

Study design

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 0.2% chlorhexidine mouthwash, rinsing twice daily with 10 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.

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.

Study burden and risks

Risk for subjects: None

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * * 18 years
- * Systemically healthy
- * * 20 teeth
- * 5 teeth per quadrant
- * No pockets >5 mm.
- * No orthodontic appliances
- * No removable (partial) dentures

Exclusion criteria

- * Use of medication possibly influencing normal gingival health
- * Pregnancy

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	04-09-2007

Enrollment: 120
Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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
CCMO	NL18362.018.07