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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/12/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
01/12/2005	Completed	[X] Results		
Last Edited 10/09/2009	Condition category Oral Health	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR274

Study information

Scientific Title

Acronym

DAGMAR - Daily Application of a Gingival Maintenance Antimicrobial Regimen

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Dental plaque

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

Results from the visual analogue scale (VAS) questionnaire to evaluate the subject's attitude towards to the used products.

Overall study start date

19/09/2005

Completion date

03/10/2005

Eligibility

Key inclusion criteria

- 1. >=18 years
- 2. Systemically healthy
- 3. >=20 teeth
- 4. 5 teeth per quadrant
- 5. No pockets >5 mm
- 6. No orthodontic appliances
- 7. No removable (partial) dentures

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

90

Key exclusion criteria

- 1. Use of medication possibly influencing normal gingival health
- 2. Pregnancy

Date of first enrolment

Date of final enrolment 03/10/2005

Locations

Countries of recruitment

Netherlands

Study participating centre Hogeschool INHOLLAND

Amsterdam Netherlands 1066 EA

Sponsor information

Organisation

Academic Centre for Dentistry in Amsterdam (ACTA) (Netherlands)

Sponsor details

Louwesweg 1 Amsterdam Netherlands 1066 EA

Sponsor type

University/education

Website

http://www.acta.nl/

ROR

https://ror.org/04x5wnb75

Funder(s)

Funder type

University/education

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2007		Yes	No