

Effectiveness of supervised toothbrushing on prevention of childish dental caries

Submission date 03/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/12/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/03/2011	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/51300-0

Study information

Scientific Title

Cost-effectiveness of supervised toothbrushing on prevention of dental caries in permanent molar first

Study objectives

To compare two techniques of direct supervised toothbrushing with fluoridated dentifrice on occurrence of caries lesions in permanent molar first.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Research Ethical Committee from Catholic University of Santos on the 20th November 2005.

Study design

An interventional community-randomised controlled single-centre trial will be conducted in six preschools with 5 - 6 year-old children.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Caries lesion on surface of permanent molar first

Interventions

Intervention group:

A modified technique of direct supervised toothbrushing with fluoridated dentifrice will be carried out in eligible children every 45 days in three randomly selected preschools (test-units). The modified technique includes professional toothbrushing on occlusal surfaces of permanent molar first carried out by trained auxiliary personnel.

Control group:

A conventional technique of direct supervised toothbrushing with same fluoridated dentifrice will be carried out in eligible children every 90 days in three preschools (control-units).

Total duration of intervention and follow-up is the same: twenty-four months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Enamel caries measured by visual exam with aid of a ball point instrument recommended by World Health Organization. The outcomes will be measured at first, 6th, 12th and 18th month.

Secondary outcome measures

Dentine caries measured by visual exam with aid of a ball-point instrument recommended by World Health Organization. The outcomes will be measured at first, 6th, 12th and 18th month.

Overall study start date

02/04/2007

Completion date

02/05/2009

Eligibility**Key inclusion criteria**

Eligible subjects with one or more sound erupted permanent molar first.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

500 pre-school children

Key exclusion criteria

Infants with condition or disease that increase caries risk.

Date of first enrolment

02/04/2007

Date of final enrolment

02/05/2009

Locations**Countries of recruitment**

Brazil

Study participating centre
Rua Carvalho de Mendonca 144 - 4th floor
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Sponsor information

Organisation
Catholic University of Santos (Universidade Catolica de Santos) (Brazil)

Sponsor details
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Sponsor type
University/education

Website
<http://www.unisantos.br>

ROR
<https://ror.org/00vcyhn10>

Funder(s)

Funder type
Government

Funder Name
State of Sao Paulo Research Foundation (Fundacao de Amparo a Pesquisa do Estado de Sao Paulo [FAPESP]) (Brazil)

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	22/03/2011		Yes	No