Effectiveness caries-preventive measures in children. A non-operative caries treatment programme and fluoride regime: a comparison.

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

Summary

ID

NL-OMON29846

Source
ToetsingOnline

Brief title
Effectiveness of a "Nexo-" and fluoride regime in the Netherlands

Condition

- Other condition

Synonym
Caries, dental decay

Health condition

gebitsaandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Caries-prevention, Children, Fluoride, non operative caries treatment programme

Outcome measures

Primary outcome

1. dmft/DMFT-scores + SIC-index changes

2. dmfs/DMFS-scores + SIC index changes

3. Costs per child / per year

Secondary outcome

4. sensitivity / specificity cariësdiagnosis with diagnodent pen compared to

X-ray photos

5. Contentment of executing dentists / inventarisation of possible bottlenecks

6. Profiles of patient-categories

Study description

Background summary

Recent studies revealed that there is an indication that the prevalence of caries in young children is becoming more of a problem lately.

Fluoride is known to be a succesfull way of preventing caries in large amounts of people. A recent study showed that a non-operative caries treatment

programme is even more succesfull, with a promissing cost-effectiveness.

Study objective

To investigate whether this model, disigned in the Danish region of Bornholm, is applicable in the Dutch situation and can reach comparable results, this study is being repaeted in a regional office for children's dental care in 's Hertogenbosch and in de region of Enschede. Comparing this method with the current situation of fluoride-application and intensivated fluoride-application.

As a satelite-survey the results of a laser-fluorescence based caries-detection device is being compared to the currently used X-ray photographs

Study design

Single blind randomised clinical trial

Children are being at random included in either group 1, 2 or 3.

group 1 Folowing the non-operative caries treatment programme, returning for their regular dental visits every 1,2 4 or 6 months, depending on their risk-assessment. resin-based sealings on indication, x-rays on indication, topical-fluoride on indication.

group 2 returning for their dental check-ups every 3 months and receiving the usual fluoride-application. otherwise not different than the usual treatments

group 3 control group: only the now usual preventive programme twice a year for checkup with the usual treatments

Intervention

group 1: (Nexo-group) Dental check-up interval assessed by the dentist individually at time of the check-up. Interval-time can vary from one month to nine months depending on age, oral hygiene level, attitude child/parent, eruptionlevel of permanent molars.

group 2: (fluoride group) Dental check up interval like current protocol (twice a year) with two additional fluoride-gel-applications a year

group 3: control group

Study burden and risks

None

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

On October 1st 2006 age of 5 years, 9 months +/- 6 months

Exclusion criteria

none

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	750
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	NL13709.029.06