Glass-ionomer-based materials for preventing carious lesions in Chinese children

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There is no difference in carious lesion development between sealants of glass-ionomer, glass-carbomer and composite resin and placed in first permanent molars after 5 years

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27411

Bron
NTR

Verkorte titel
N/A

Aandoening

dental caries; carious lesion development; caries prevention; sealants.

Ondersteuning

Primaire sponsor: initiator
Overige ondersteuning: finances received from
- KNAW, the Netherlands;
- College of Dental Sciences, the Netherlands;
-School of Stomatology, Wuhan, China.
Material support received from 3MESPE, China

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Prevention of carious lesions in first permanent molars

Toelichting onderzoek

Achtergrond van het onderzoek

The study inclusion criteria consist of molar teeth in the mandible that are at high risk for developing carious lesions in pits and fissures of occlusal and buccal tooth surfaces of young children. The number of children included in the study have been determined through power calculations and randomly divided over 3 parallel groups: a resin, a high-viscosity glass-ionomer and a glass-carbomer sealant group. The different sealant materials have been applied using the manufacturers' Direction for Use.

Sealants will be periodically (0.5, 1, 2, 3, 4 and 5 years) evaluated by independent and calibrated evaluators using the ART criteria.
The wear pattern over time will be assessed from replicas produced from impressions taken at each of the 6 evaluation times. The measurements will include loss of volume and height obtained through using 3-D laser images and relevant computer software. Survival analysis and parametric tests will be applied to assess the type of sealant that prevents carious lesion development in pits and fissures of these children best. Cost data have been collected using activity sampling procedure.

Doel van het onderzoek

There is no difference in carious lesion development between sealants of glass-ionomer, glass-carbomer and composite resin and placed in first permanent molars after 5 years

Onderzoeksopzet

Clinical evaluation after 6 months, 1, 2, 3, 4, and 5 years.

Each time of evaluation an impression of a sample of sealed teeth by group will be taken.

Onderzoeksproduct en/of interventie

Four sealant groups.

1. Composite resin = positive control

2. Glass-ionomer, improved version = experimental

3. Glass-ionomer plus light-curing = experimental

4. Glass-carbomer, new material = experimental

First permanent molars will be sealed.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy children with at least 2 cavitated teeth in primary dentition and patent pits and fissures or presence of enamel carious lesion in first permanent molar (high caries risk group)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Healthy children with less than 2 cavitated teeth in their primary dentition, and those with two or more cavitated primary teeth but with shallow pits and fissures in the first permanent molars.

2. Permanent molars with cavities

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-04-2008
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1382
NTR-old	NTR1441
Ander register	: 08CDP011
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A