

Is it effective and cost-effective to seal dental caries instead of "drilling and filling"?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21227

Source

Nationaal Trial Register

Health condition

Dental caries progression, caries lesion management, cost-effectiveness

Sponsors and support

Primary sponsor: University Medical Centre Groningen. Centre for dentistry and oral hygiene. Groningen, The Netherlands.

Source(s) of monetary or material Support: ZonMW, Den Haag, The Netherlands

Intervention

Outcome measures

Primary outcome

- first-attempt success rate

Secondary outcome

- caries progression after two years

- cost-effectiveness from both a medical and societal perspective
- differences in QALYs (CHU-9D)
- differences in dental fear (CFFS-DS)

Study description

Background summary

The past 5 years, there is gaining evidence that occlusal dental caries can be inhibited or stopped by sealing the lesion rather than removing all carious tissue and placing a restoration.

This study aims to assess the effectiveness and cost-effectiveness of sealing occlusal ICDAS 3 and 4 lesions by comparing the sealing method with care as usual (placing a restoration).

Study objective

Dental caries lesions (with ICDAS Codes 3 and 4) can be treated by sealing, offering a less invasive and less costly treatment option with the same results as preparation and restoration of the carious lesions.

Study design

T=0: start of intervention

T=1: control after 12 months

T=2: end of the trial

Intervention

Intervention group:

cleaning occlusal surface with rotating brush pumice, isolation of tooth (rubberdam), placement of resin-based sealant after etching

Control group (care as usual)

local anesthetic, isolation (rubberdam), preparation / excavation with rotating instruments, restoration with composite resin or compomer restoration material.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

Age 3-18 years

Caries lesions in occlusal surface

Lesion stage ICDAS 3 and 4

Exclusion criteria

Under 3 years / over 17 years

Caries lesions in other surfaces

Lesion stage ICDAS 0, 1, 2, 5 and 6

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2017
Enrollment:	300
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion	
Date:	24-07-2017
Application type:	First submission

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
NTR-new	NL6405
NTR-old	NTR6580
Other	ZonMw, 's Gravenhage : 843001810

Study results