Secondary caries in situ: minimal gap size and MMP inhibitor

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44491

Source
ToetsingOnline

Brief title
Minimal gap size

Condition

- Other condition

Synonym
caries adjacent to restorations, recurrent caries

Health condition

caries

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: in situ model, minimal gap size, MMP inhibitor, secondary caries

Outcome measures

Primary outcome

Lesion depth (µm) and mineral loss (µm.vol%) of (secondary) caries wall lesions

Secondary outcome

N.A.

Study description

Background summary

Recent research has shown that secondary caries can develop in smaller gaps than originally thought. In the in situ study of Kuper et al. (2014) it was shown that even in a gap of 68 µm secondary caries wall lesions could develop, compared to the originally assumed gap size of 225 µm (Thomas et al., 2007) or 400 µm (Kidd et al., 1995). However, not in all volunteers wall lesions developed in all gaps. It was observed that high caries risk patients showed more often wall lesions in smaller gaps than low caries risk patients. So it is hypothesized that wall lesion development may exhibit a threshold for gap size, possibly depending on the caries risk of the patient. The first rationale of this study is to investigate what the threshold gap size is for secondary caries development and whether the caries risk of patients influences this threshold.
The other aim of this study is to investigate the role of MMP-inhibitors on secondary caries development. Matrix metalloproteinases (MMP*s) are present in saliva, dentin, and dentinal fluid and may be capable of degrading extracellular matrix components. They can cause loss of collagen in the adhesive hybrid layer under composite restorations (Visse and Nagase, 2003) and therefore play a role in the secondary caries pathogenesis. There are multiple in vitro and in vivo reports showing that the longevity of the adhesive interface is increased when nonspecific enzyme-inhibiting strategies are used. Different chemicals (i.e. chlorhexidine, galardin and benzalkonium chloride)

have been successfully employed as therapeutic primers. Therefore, the second rationale of this study is to investigate the effect of chlorhexidine as MMP-inhibitor on the development of secondary caries in situ.

Study objective

Aims of this in situ study are: i) to investigate whether there is a threshold in gap size for secondary caries to develop and additionally to link the level of secondary caries formed with the caries risk of the volunteers, and ii) to evaluate the role of MMPs inhibitor (2% CHX) in the secondary caries lesion development and progression.

Study design

a mono-center, double blind in situ study, with split-mouth design

Study burden and risks

The burden for participating volunteers exists of wearing a removable appliance in which the tooth samples are placed during a period of 3 weeks, for 24 hours per day. Swallowing one of the tooth samples is a relative risk. Securing the tooth samples in the slots of the appliance with the help of composite material in an undercut has proven to minimize this risk in earlier studies (NL33528.01.11).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- subjects able to wear a removable appliance for 3 weeks, 24 hrs per day
- adults (>=18 years) with healthy dentition

Exclusion criteria

- active caries
- periodontitis DPSI > 2
- ASA > 2
- removable prosthetic appliance

Study design

Design

Study type: Observational non invasive

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	16

Type:	Actual

Ethics review

Approved WMO Date:	30-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56622.091.16