

# Secondary caries in situ: minimal gap size and MMP inhibitor

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 ( $\mu\text{m}$ ) and mineral loss ( $\mu\text{m.vol\%}$ ) 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  $\mu\text{m}$  secondary caries wall lesions could develop, compared to the originally assumed gap size of 225  $\mu\text{m}$  (Thomas et al., 2007) or 400  $\mu\text{m}$  (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 ( $\geq 18$  years) with healthy dentition

### Exclusion criteria

- active caries
- periodontitis  $\text{DPSI} > 2$
- $\text{ASA} > 2$
- 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**

CCMO

**ID**

NL56622.091.16