

# In situ remineralisation of enamel and dentine after the use of amine fluoride dentifrice and amine fluoride mouthrinse.

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The goal of this research is to see whether offering fluoride three times a day enhances the remineralisation of an early carious lesion more than fluoride twice a day.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32230

### Source

ToetsingOnline

### Brief title

In situ remineralisation of enamel and dentine.

### Condition

- Other condition

### Synonym

cavity, toothdecay

### Health condition

caries

### Research involving

Human

## Sponsors and support

**Primary sponsor:** GABA Benelux

**Source(s) of monetary or material Support:** bedrijf

## Intervention

**Keyword:** caries, fluoride, mouthrinse, remineralisation

## Outcome measures

### Primary outcome

mineralisation of enamel/dentine

difference in fluorescence

level of fluoride in enamel/dentine

### Secondary outcome

amount of fluoride of dental plaque and saliva

## Study description

### Background summary

To patients that are at high risk of getting caries, dentists often recommend an extra period of fluoride exposure a day, besides the usual brushing of the teeth with a fluoride dentifrice twice a day. It was already demonstrated that the surface of a tooth contains more fluoride after additionally rinsing with a fluoride mouthrinse. It is not shown that it as well enhances the remineralisation of an early cariouslesion. We will investigate that in this study.

### Study objective

The goal of this research is to see whether offering fluoride three times a day enhances the remineralisation of an early cariouslesion more than fluoride twice a day.

### Study design

In the buccal flanges of the partial prosthesis in the lower jaw of the

participants, specimens of enamel or dentine will be placed. On the specimens an early carious lesion is made. The participants need to follow an oral hygiene protocol that says they have to brush twice a day with fluoride toothpaste and rinse with a fluoride- or a control mouthrinse. After the experimental period the specimens will be removed from the prosthesis and analysed for the mineral content. Besides this, samples of saliva and plaque will be taken to analyse the amount of fluoride.

### **Intervention**

Participants brush their teeth twice a day with a fluoride dentifrice and additionally rinse with a fluoride- or control mouthrinse once a day.

### **Study burden and risks**

The burden is the extra visits to the clinic and executing the oral hygiene protocol (which people normally already execute for most part). Participating means no health risks for the participants.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

partial prosthesis on the lower jaw

enough thickness of the resin of the prosthesis

age > 18 years

### Exclusion criteria

not enough thickness of the resin of the prosthesis

not being able to deal with the oral hygiene protocol

no partial prosthesis in the lower jaw

age < 18

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2008
Enrollment:	14
Type:	Actual

## Ethics review

Approved WMO

Date: 28-04-2008

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	NL19894.029.07