

# The use of fluoride rinse for caries prevention during the orthodontic treatment with fixed appliances

Published: 09-07-2009

Last updated: 05-05-2024

Our aim is to find methods to effectively reduce the caries incidence during orthodontic treatment with fixed appliances. A secondary aim is to study the effect of fixed orthodontic appliances on the plaque ecology in relation to caries development...

<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-OMON33004

### Source

ToetsingOnline

### Brief title

fluoride rinse for caries prevention in orthodontics

### Condition

- Other condition

### Synonym

Cariës, tooth decay

### Health condition

cariës

### Research involving

Human

## Sponsors and support

**Primary sponsor:** GABA International

**Source(s) of monetary or material Support:** GABA international

## Intervention

**Keyword:** Caries prevention, Fluoride, orthodontics

## Outcome measures

### Primary outcome

Number of caries lesions as found by visual inspection, extent of lesions expressed by their fluorescence loss and lesion area (QLF).

### Secondary outcome

plaque composition and aciduricity.

## Study description

### Background summary

In a previous study (approved AMC MEC01/099#01.17.594) we found that 97% of study participants had caries on the buccal surfaces after removal of fixed appliances, with on average 30% of buccal surfaces affected[Boersma et al., 2005]. Forty-nine percent of caries lesions remained as permanent scars while fifteen percent of lesions had received or were in need of restorative care 2 years into the retention period[Mattousch et al., 2007]. No clear evidence exists on which preventive measures are effective in reducing caries incidence in this specific patient population, or how to reminisce caries that has developed during orthodontic treatment[Benson et al., 2005].

### Study objective

Our aim is to find methods to effectively reduce the caries incidence during orthodontic treatment with fixed appliances. A secondary aim is to study the effect of fixed orthodontic appliances on the plaque ecology in relation to caries development.

### Study design

The study will be performed as a double blinded randomized clinical trial.

## **Intervention**

Participants during treatment with orthodontic appliances will be put on a rigid oral hygiene program with regularly available fluoride rinse (elmex CARIES PROTECTION dental rinse), or rigid oral hygiene supplemented with a placebo rinse without fluoride.

## **Study burden and risks**

Subjects treated with fixed orthodontic appliances are at increased caries risk and the caries progresses faster than normal. For this specific type of lesions, little evidence on the most effective way of caries prevention and remineralization exists. The predominant cause for caries is believed to be a lack of adequate oral hygiene. The patients volunteering as participants in the study are expected to benefit from an enforced oral hygiene, given them extra attention at the loss of some time, which should result in less caries.

## **Contacts**

### **Public**

GABA International

Grabetsmattweg  
CH-4106 Therwil  
CH

### **Scientific**

GABA International

Grabetsmattweg  
CH-4106 Therwil  
CH

## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

### Inclusion criteria

- \* Subject is enrolled as patient at the orthodontic clinic of ACTA,
- \* Subject is scheduled to receive orthodontic treatment with fixed appliances for a period of at least one year.
- \* Subject is between 10 and 18 years old at the start of the study.
- \* Subject is in general good health except for the orthodontic treatment need.
- \* Subject, and also parents or guardian, have signed an informed consent form prior to the start of the study.
- \* Note that all orthodontic patients, prior to treatment with fixed appliances, need to maintain oral hygiene levels such that they fall into oral hygiene class 1(good) or 2(adequate).

### Exclusion criteria

- \* Subject is younger than 12 years old or older than 18 years old at start of the study.
- \* Subject is mentally not capable to understand and follow instructions.
- \* Subject has received orthodontic treatment with fixed appliances before.
- \* Subject suffers from a systemic illness.
- \* Subject suffers from caries in need of restorative care on the buccal surfaces.
- \* Subject uses other fluoride-containing products

## Study design

### Design

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2009
Enrollment:	120
Type:	Actual

## Ethics review

Approved WMO	
Date:	09-07-2009
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	NL26663.029.09