Study of the efficacy of calcium and phosphate containing fluoride paste and a placebo paste to promote remineralisation of caries developed during orthodontic treatment with fixed appliances.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30955

Source
ToetsingOnline

Brief title
remineralization of caries developed during orthodontic treatment.

Condition

- Other condition

Synonym
caries, tooth decay

Health condition

caries

Research involving
Human

Sponsors and support

Primary sponsor: Academisch centrum voor tandheelkunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: caries, orthodontics, plaque ecology, remineralisation

Outcome measures

Primary outcome

Number of Caries lesions, change in lesion extent expressed by their

fluorescence loss and lesion area over a one-year study period.

Secondary outcome

Plaque composition and acidogenicity

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 to remineralize caries that has developed during orthodontic treatment.

Study objective

Our aim is to find methods to effectively remineralize caries lesions that have developed during orthodontic treatment. A secondary aim is to study the effect of fixed orthodontic appliances on the plaque ecology in relation to caries

development in this patient population.

Study design

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

Intervention

Participants with caries on the buccal surfaces upon removal of the fixed appliances will be put on a rigid oral hygiene program. One-half of subjects will also receive a a paste containing Casein Phosphopeptide-Amorphous Calcium Phosphate (CPP-ACP) and fluoride for daily use at home. The other half of subjects will receive a placebo paste.

Study burden and risks

Subjects treated with fixed orthodontic appliances are at increased caries risk and the caries progresses faster than normal. After removal of the fixed appliances the caries lesions only limited improvements are seen. For this specific type of lesions, little evidence on the most effective way of caries remineralization exists. 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 (oral hygiene instructions, when necessary cleaning) allowing for active remineralization of existing lesions. The CPP-ACP paste with fluoride may enhance the effect of rigid oral hygiene on remineralization.

Contacts

Public
Academisch centrum voor tandheelkunde

Louwesweg 1
1066EA Amsterdam
NL
Scientific
Academisch centrum voor tandheelkunde

Louwesweg 1
1066EA Amsterdam
NL

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,
and receives orthodontic treatment with fixed appliances and is scheduled for debracketing.
Subject is between 12 and 18 years old at the start of the study.
Subject, and also a parent or guardian, have signed the informed consent form prior to the start of the study.
Subjects have at least two detectable caries lesions on their buccal surfaces immediately after debracketing.

Exclusion criteria

Subject is younger than 12 years old or older than 18 years old.
Subject is mentally not capable to understand and follow instructions.
Subject suffers from a systemic illness.
Subject is milk protein intolerant, because this may provoke an allergic reaction to the CPP-ACP paste.
Subject has caries lesions that need restorative care.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2007
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

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	NL19226.029.07