

Fluoride rinse for caries prevention in orthodontics.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24509

Source

Nationaal Trial Register

Brief title

N/A

Health condition

caries development during orthodontic treatment with fixed appliances.

Sponsors and support

Primary sponsor: GABA international

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

Intervention

Outcome measures

Primary outcome

1. Caries incidence;
2. Plaque ecology shifts.

Secondary outcome

1. Caries pathogens;
2. Bleeding score;
3. Caries severity.

Study description

Background summary

N/A

Study objective

Fluoride rinse helps prevent caries more than optimal tooth cleaning alone.

Study design

Just prior to ortho treatment with fixed appliances, 6 and 12 weeks thereafter, then every 6 months until debond, before (plaque) and after debond (caries) and 6 and 12 months thereafter.

Intervention

Elmex Cariesprotection fluoride rinse and a placebo rinse.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subject is enrolled as patient at the orthodontic clinic of ACTA;
2. Subject is scheduled to receive orthodontic treatment with fixed appliances for a period of at least one year;
3. Subject is between 12 and 18 years old at the start of the study;
4. Subject is in general good health except for the orthodontic treatment need;
5. Subject, and also parents or guardian, have signed an informed consent form prior to the start of the study;
6. 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

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	25-05-2009
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion	
Date:	15-05-2009
Application type:	First submission

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
NTR-new	NL1707

Register	ID
NTR-old	NTR1817
Other	METc VU / ABR / ORTCAR : 026/09 / NL26663.029.09 / 2008-01
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A