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Is a plaque-identifying toothpaste useful for reducing plaque in children (age 12-16 years) treated with fixed orthodontic appliances?

Submission date
22/04/2022

Recruitment status
No longer recruiting

Registration date
03/05/2022

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Orthodontic treatment with braces (fixed appliance) makes it more difficult for patients to clean their teeth properly. Plaque could remain on the teeth which ultimately could cause visible white spot lesions of the enamel around the brackets. A plaque-colouring toothpaste that colours the plaque that remains on the tooth surfaces could help the patient to brush all plaque away as it is easier to see for them where should be brushed.
The aim of this study is to investigate if brushing with a plaque-colouring toothpaste as compared to brushing with a normal toothpaste leads to less plaque on the teeth in children who are treated orthodontically with fixed braces.

Who can participate?
Children between 12 and 16 years of age who have fixed braces on at least all six upper and lower front teeth can participate in this study. Children should be healthy, and not allergic to substances in the kinds of toothpaste that are used in the study. The braces should be on the teeth for at least three months prior to the beginning of the study.

What does the study involve?
The amount of plaque on the teeth will be compared between two groups: brushing with or without a plaque-colouring toothpaste. Both groups brush two times a day, which is the standard protocol for children having braces.
Plaque is measured at baseline and at 6 weeks using photographs of the mouth.

What are the possible benefits and risks of participating?
The benefit is the possibility of reduced plaque.
No risks.

Where is the study run from?
Orthodontics department of the University Medical Center Groningen (UMCG) (the Netherlands)

When is the study starting and how long is it expected to run for?
April 2021 to September 2022

Who is funding the study?
University Medical Center Groningen (UMCG) (the Netherlands)

Who is the main contact?
Sebastiaan Pieter van Doornik, s.p.van.doornik@umcg.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UMCG METc 2021.516

Study information

Scientific Title
The effect of a plaque-identifying toothpaste on the amount of plaque in 12-16-year-old patients treated with fixed orthodontic appliances: a randomized, double-blind, controlled clinical trial

Study objectives

Primary objective
The plaque-identifying toothpaste has a (reducing) effect on the amount of plaque compared to the non-staining toothpaste in patients with fixed orthodontic appliances aged 12 to 16 years.

Secondary objective
There is a difference in the user experience of the plaque- identifying toothpaste compared to the non-staining toothpaste in patients with fixed orthodontic appliances aged 12 to 16 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reviewed 16/09/2021, Medical Ethics Review Board University Medical Center Groningen (P.O. Box 30 001, 9700 RB, Groningen, The Netherlands, metc@umcg.nl) ref: METc 2021.516 The Medical Ethics Review Board of the University Medical Center Groningen (METc UMCG) has discussed the mentioned protocol and considered that the research does not fall within the scope of the Medical Research Involving Human Subjects Act (WMO). Therefore the METc UMCG concluded that the study did not need a WMO approval before the start of the research.

Study design
Single center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Prevention of plaque accumulation around brackets in patients with a malocclusion undergoing orthodontic fixed appliance treatment.

Interventions
A prospective, randomised, double-blind, placebo-controlled trial will be conducted at the orthodontic department of the University Medical Center Groningen, the Netherlands.
The G*Power program (G*Power, 3.1, Heinrich Heine Universität Düsseldorf, Dusseldorf, Germany) was used to determine the sample size of at least 66 patients and accounting for dropouts it was decided to include a total of at least 80 patients.
Block randomization based on manual or electric toothbrush usage will be used, each block consisting of 6 participants (3 intervention, 3 placebo), all blinded and randomized.

The two-arm intervention design will consist of a 6-week self-administration of a plaque identifying toothpaste (intervention) or a color-matched toothpaste (placebo) at least twice a day.

Before the start of the study, opaque tubes (75ml) were randomly two-digit number-coded by an independent researcher not related to the trial according to the block randomization scheme and filled with the intervention or placebo toothpaste.
After informed consent, patients (age 12-16) treated with fixed orthodontic appliances for at least three months will be recruited.
At baseline (T0), Quantitative Light Fluorenes (QLF) pictures, demographic data, brushing type (electric or manual), additional oral care, Decayed, Missing, and Filled Permanent Teeth (DMFT), intra-oral light photographs (complementary to the QLF image) will be recorded.
After 6 weeks at the end of the study (Tl), QLF pictures, intra-oral light photographs, therapy compliance and a user experience questionnaire will be recorded.

Intervention Type
Other

Primary outcome measure
Plaque is measured with Quantitative Light Fluorescence as a surface measurement on intra-oral photographs of the buccal tooth surfaces in the anterior region (lower and upper cuspid to cuspid). At baseline (T0) and at 6 weeks after baseline (Tl, end of study).

Secondary outcome measures
User experience questionnaire at 6 weeks after baseline

Overall study start date
26/04/2021

Completion date
01/09/2022

Eligibility

Key inclusion criteria
1. Patients who are treated in the Orthodontics department of the University Medical Center Groningen (UMCG)
2. Age category from 12 to 16 years
3. Under treatment with fixed orthodontic appliances in both jaws for at least three months
4. Twelve permanent anterior elements, namely from cuspid to cuspid, present
5. No syndromic or other craniofacial anomalies

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
80

Total final enrolment
83

Key exclusion criteria
1. Participants from the same family
2. Allergy to one of the components of the toothpastes used
3. Intervention or appointment with a dental professional (prevention assistant, dental hygienist, dentist or specialist) during the study

Date of first enrolment
25/10/2021

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Orthodontics department of the University Medical Center Groningen (UMCG)
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Sponsor information

Organisation
University Medical Center Groningen

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/EN

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/03/2024

Individual participant data (IPD) sharing plan

Will be stored in Redcap UMCG
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Stored in non-publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	in Dutch	26/04/2022	03/05/2022	No	No
Results article		28/02/2025	28/02/2025	Yes	No