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An in situ study to determine the effects of calcium-based toothpaste in orthodontic patients

Submission date
18/01/2014

Recruitment status
No longer recruiting

Registration date
27/01/2014

Overall study status
Completed

Last Edited
29/03/2018

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
White spots on the front of the teeth are a potential side effect of fixed orthodontic brace treatment. The brackets, wires and bands reduce oral hygiene of tooth surfaces which can lead to plaque accumulation. This may result in mineral loss from the tooth surface which shows as a white spot on the tooth. This process is reduced or eliminated by effective oral hygiene and a suitable diet. Calcium-based toothpastes have been suggested as an approach to improve the damaged tooth surfaces. This study aims to find out about the re-mineralising abilities of calcium-based toothpastes.

Who can participate?
Male and female patients aged between 12 and 17 who are receiving orthodontic treatment at the University of Liverpool Dental Hospital, UK

What does the study involve?
A human enamel sample that has been demineralised in the lab will be prepared and split into three samples. Two will be used on the patient and one will be kept in the lab as a control. Mineral content will be measured in all the samples. The participant will have a carrier with the prepared enamel sample securely attached to the back part of the brace. Each participant is provided with the relevant toothpastes in a random order and provided information on brushing their teeth. In total two carriers will be attached to the brace with two different types of toothpastes to use. One of the regimes will involve brushing with a pea-sized amount of fluoride toothpaste for 2 minutes twice a day. The other regime will involve brushing with a pea-sized amount of fluoride toothpaste for 2 minutes twice a day in addition to a calcium-based toothpaste being applied to the teeth for 5 minutes twice a day.

What are the possible benefits and risks of participating?
The benefit of taking part in the study is the use of an additional toothpaste over a four-week period may help to reduce or improve areas of tooth demineralisation. The only burden to the patient will be the extra time added to their normal appointment which involves inserting and removing the sterilised enamel carrier (5 minutes). It will not affect how the brace works.

Where is the study run from?
The study will be run in the Liverpool University Dental Hospital, UK

When is the study starting and how long is it expected to run for?
The study is due to start in March 2014 and will last for approximately 5 months.

Who is funding the study?
University of Liverpool, UK

Who is the main contact?
Dr Norah Flannigan, nlf@liverpool.ac.uk
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Contact information

Type(s)
Scientific

Contact name
Dr Norah Flannigan

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPP- ACP toothpaste trial v1.2

Study information

Scientific Title
An in situ study to determine the effects of Casein PhosphoPeptide Amorphous Calcium Phosphate toothpaste in orthodontic patients

Acronym
CPP-ACP

Study objectives
Dental caries is the process of localised chemical dissolution affecting hard dental tissue due to metabolic events taking place within the surrounding biofilm. Organic acid production from bacterial fermentation of dietary sugars results in a shift in the dynamic balance of demineralisation-remineralisation with a net loss of tooth substance. This complex process is directly affected by the presence of microbial species, fermentable carbohydrates, fluoride ions, saliva composition and flow rate, buffering capacity and time. Other contributory secondary factors include education, social class, attitudes and behaviour.

This study will test the null hypothesis that there is no difference between the remineralising abilities of GC Tooth Mousse™ and normal fluoride toothpastes in orthodontic patients. Therefore there will be no statistically significant difference between volume mineral loss (ΔZ), lesion depth and lesion width.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Liverpool Central, REC reference: 13/NW/0742, protocol number: UoL000980, IRAS project ID: 128420

Study design
Randomized cross-over in situ study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request patient, parent and child information sheets

Health condition(s) or problem(s) studied
Dental caries

Interventions
Prepared enamel lesions are placed in situ. Fluoridated toothpaste and fluoridated toothpaste plus GC ToothMousse™ will be given in a random order.

Visit 1: pre-trial wash-out (4 weeks)
Routine orthodontic exam
Patient provided with standard fluoride toothpaste, toothbrush and instructions

Visit 2: treatment A (4 weeks)
Routine orthodontic exam
Carrier with enamel specimen will be attached to lower premolar region
Treatment A paste is given to patient with instructions on its use

Visit 3: mid-treatment wash-out (4 weeks)
Routine orthodontic exam
Carrier with enamel specimen removed and sent for analysis
Patient provided with the standard fluoride toothpaste and instructions

Visit 4: treatment B (4 weeks)
Routine orthodontic exam
New carrier with enamel specimen attached
Treatment B pastes given to patient with instructions on its use

Visit 5: trial competition
Routine orthodontic exam
Carrier with enamel specimen removed and sent for analysis

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Using Transvere MicroRadiography the mineral content of the enamel specimen will be carried out at baseline (before the trial begins) and then 4 weeks after being placed in the mouth. The following parameters will be analysed:
1. Mineral loss ΔZ (vol%μm)
2. Lesion depth Ld (μm) and
3. Lesion width Lw (μm)

Secondary outcome measures
After the trial has finished, using the previously collected data the percentage change in mineral loss, lesion depth and lesion width is calculated

Overall study start date
01/03/2014

Completion date
01/07/2014

Eligibility

Key inclusion criteria
The subjects are required:
1. To be between the ages of 12 to 17 years
2. To have adequate space between their last premolar and 1st standing molar to allow

placement of the carrier on the archwire
3. To be in a suitable rigid archwire to allow placement of carrier
4. To be in good general health and oral health

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
The subjects will be excluded if:
1. They are allergic to milk products
2. They are taking or have taken antibiotics in the last 2 months
3. Unable to maintain adequate oral hygiene

Date of first enrolment
01/03/2014

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool University Dental Hospital
Liverpool
United Kingdom
L3 5PS

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
c/o Alex Astor
Research Support Office
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3 Brownlow St
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Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name
University of Liverpool (UK) - DDSC bench fees fund

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

07/02/2017: Results presented in thesis 2015 https://livrepository.liverpool.ac.uk/203446

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No
HRA research summary			28/06/2023	No	No