

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

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| Submission date 18/01/2014 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 27/01/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 29/03/2018 | Condition category Oral Health | <input type="checkbox"/> Individual participant data |

Plain English Summary

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

Prof Susan Higham

Mr Andrew Garry, andrew.garry@liverpool.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Norah Flannigan

Contact details

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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 hypothesis

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

Condition

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 Transverse 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 L_d (μm) and
3. Lesion width L_w (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

Overall study end date

01/07/2014

Eligibility

Participant 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

Participant 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

Recruitment start date

01/03/2014

Recruitment end date

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
2nd Floor Block D Waterhouse Building
3 Brownlow St
Liverpool
England
United Kingdom
L69 3GL

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 |