

Effect of dental varnishes on root caries in patients with xerostomia

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| Submission date 09/02/2016 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 10/02/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 03/07/2019 | Condition category Oral Health | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Root caries are cavities that form on the roots of the teeth. Xerostomia (dry mouth) is considered as a primary cause for root caries in older people, as the reduction in saliva flow and resulting increase in mouth acidity leads to loss of minerals from the tooth surface. CPP-ACP is a type of protein derived from milk that enhances the action of fluoride. The aim of this study is to test two different dental varnishes containing fluoride with or without CPP-ACP for the treatment of root caries in patients with xerostomia.

Who can participate?

Patients aged 18 and over attending the Dry Mouth clinic at the Barts and The London Dental hospital or the Diabetic clinic.

What does the study involve?

The participants are randomly divided into two groups. One group is treated with dental varnish containing fluoride. The other group is treated with dental varnish containing fluoride and CPP-ACP. At the start of the study all participants undergo assessments of mouth dryness, saliva, root caries and plaque, and the varnish is applied. The saliva test, root caries and plaque assessment and varnish application are repeated at follow-up visits after 3, 6 and 12 months.

What are the possible benefits and risks of participating?

Participants will benefit from a clinical examination of their mouth which will verify if they are suffering from oral dryness or root decay. Participants will receive varnish application which is a pain-free treatment, oral hygiene instructions, and free standard toothpastes with medium toothbrushes during the study period. There are no reported side effects related to the use of dental varnishes for the management of tooth decay. The only issue is that the dental varnish may fail to manage your root decay, subsequently either restorative treatment ("drilling and filling") or extraction of the decayed tooth may be required.

Where is the study run from?

NHS Trust, Barts and The London Dental Hospital, School of Medicine and Dentistry (UK)

When is the study starting and how long is it expected to run for?
June 2016 to January 2018

Who is funding the study?
Queen Mary University of London (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of dental varnishes with casein phosphopeptide–amorphous calcium phosphate (CPP-ACP) for the management of root caries in patients with xerostomia: a 12-month randomised clinical trial

Study objectives

There is a difference in the efficacy between two dental formulas either containing CPP-ACP and fluoride or fluoride only on the management of root caries in Xerostomia patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Office for Research Ethics Committees Northern Ireland (ORECNI), 07/06/2016, 16/NI/0101

Study design

Randomised double-blinded controlled clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Root caries

Interventions

1. Test group will receive dental varnish with CPP-ACP and fluoride (MI varnish, GC)
2. Control group will receive dental varnish with fluoride only (NUPRO Varnish, DENTSPLY)

After the recruitment phase each participant will undergo baseline assessments including oral dryness scoring, saliva test, root caries assessment, plaque index and dental varnish application.

Follow-up visits will be after 3, 6 and 12 months. The saliva test, root caries assessment, plaque index and varnish application will be repeated though these three visits.

Intervention Type

Other

Primary outcome measure

Change in root caries severity index (scores 0, 1, 2, 3 and 4) at baseline and after 3, 6, and 12 months

Secondary outcome measures

1. Change in texture, hardness, cavitation, colour, size and distance from the gingivae at baseline and after 3, 6, and 12 months

2. Change in the fluorescence values at baseline and after 3, 6, and 12 months
3. Correlation of the severity index and fluorescence values at baseline and after 3, 6, and 12 months
4. Correlation of the severity index and saliva properties, including buffering capacity and resting pH, at baseline and after 6 and 12 months
5. Correlation of the severity index and plaque index at baseline and after 3, 6, and 12 months

Overall study start date

01/06/2016

Completion date

01/01/2018

Eligibility

Key inclusion criteria

1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female ≥ 18 years of age
3. Minimum one primary root caries (PRC), which is accessible for the diagnostic procedure
4. Participants who agree to return for assessments during the study period
5. Participants who are capable of giving informed consent
6. Saliva sample test showing a quantitative change in unstimulated whole saliva; ≤ 0.16 mL/min
7. Ability to carry out oral hygiene practice instruction
8. Participants who agree to use the standard dentifrice (Aquafresh, GSK, 1450 ppm fluoride) with a medium sized toothbrush (Oral-B) that will be provided by the research team
9. Participants are not involved in another clinical study investigating the oral care products
10. Participants not using any other mouthwash/dentifrice/gels/chewing gums/lozenges containing test ingredients and fluoride
11. In the Investigator's opinion, is able and willing to comply with all trial requirements
12. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the trial
13. Medically allowable to undergo the baseline and follow-up assessments

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80 participants with 40 for each group

Total final enrolment

80

Key exclusion criteria

1. No active primary root carious lesions
2. Presence of chronic/aggressive periodontal disease concerning the test tooth in the study tooth (purulent exudates, tooth mobility, and/or extensive bone loss)
3. Participation in another dental study testing different dental products during the previous three months and during the study period
4. Any condition, which in the opinion of the investigator, would preclude participation by the subject (such as cross-infection control risk)
5. Cognitive defect due to mental illness, depression, Alzheimer's disease, or dementia
6. Secondary root carious lesion
7. Hypersensitivity to either milk or one of the test products
8. Test tooth with untreated cavitated proximal or occlusal caries
9. Patient using any other topical agent that may affect the results such as mouthwash, chewing gum and lozenge with active ingredients or antibacterial agents
10. Female participant who is pregnant, lactating or planning pregnancy during the course of the trial
11. Significant renal or hepatic impairment
12. Scheduled elective surgery or other procedures requiring general anaesthesia during the trial
13. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial
14. Participants who are prescribed for long-term systematic antibiotics

Date of first enrolment

01/06/2016

Date of final enrolment

01/01/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

NHS Trust, Barts and The London Dental Hospital, School of Medicine and Dentistry

United Kingdom

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Sponsor information

Organisation

Queen Mary University of London (UK)

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Sponsor type

University/education

ROR

<https://ror.org/026zzn846>

Funder(s)**Funder type**

University/education

Funder Name

Queen Mary University of London

Alternative Name(s)

Queen Mary Uni of London, Queen Mary, Queen Mary and Westfield College, QMUL, QM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

The 6 and 12 months outcomes mentioned above will be statistically analyzed to be published in dental journals and/or presented at conferences.

Intention to publish date

01/01/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |