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Effect of dental varnishes on root caries in patients with xerostomia

Submission date
09/02/2016

Recruitment status
No longer recruiting

Registration date
10/02/2016

Overall study status
Completed

Last Edited
03/07/2019

Condition category
Oral Health

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

Primary study design
Interventional

Study design
Randomised double-blinded controlled clinical trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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 constant

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 another other 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Study participating centre
NHS Trust, Barts and The London Dental Hospital, School of Medicine and Dentistry
United Kingdom
E1 2AD

Sponsor information

Organisation
Queen Mary University of London (UK)

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, The London Hospital Medical College, St Bartholomew's Hospital Medical College, Westfield College, East London College/Queen Mary College, QMUL, QM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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