

Dental remineralization: effects of fluoride and calcium phosphate-based varnishes on the saliva and plaque index of children at high risk of tooth decay

Submission date 21/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/03/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

When dental plaque is not regularly removed, bacteria break down sugars in the diet forming acids as by-products. Lactic acid is the main acid involved in caries (tooth decay). As acids accumulate minerals are lost from the surface layer of the tooth. The imbalance in demineralization/remineralization favours the loss of calcium and phosphate from the teeth. Saliva contains the most important microelements for the remineralization and maturation of dental tissue and plays a crucial role in maintaining the oral environment. Fluoride is the agent par excellence in preventing and detaining cavities. However, remineralization may be hampered by limited levels of calcium and phosphate, and new products have been developed to ensure a constant supply. Two of the most used products are amorphous calcium phosphate stabilized with casein phosphopeptide (CPP-ACP) and tricalcium phosphate modified by fumaric acid (FTCP). The aim of this study is to study the effects of coating with CPP-ACP (MI Varnish) and FTCP (Clinpro White Varnish), applied quarterly to children at high risk of cavities, on pH, lactic acid, salivary trace elements, bacteria and plaque for 12 months.

Who can participate?

Children aged 4-12 years attending the Integrated Child Dentistry Clinic of the University of Murcia for checkups or dental treatment at a high or extreme risk of caries

What does the study involve?

Participants are randomly allocated to be treated with one of two varnishes – MI Varnish (CPP-ACP with sodium fluoride 5%) and Clinpro White Varnish (FTCP with sodium fluoride 5%) – or a placebo (dummy) varnish every 3 months for 12 months. Saliva samples are taken at the start of the study and every 3 months. The researchers assessed changes in pH, lactic acid concentrations, trace elements and bacterial concentration in saliva. They also assessed plaque and caries.

What are the possible benefits and risks of participating?

The individuals participating in the study are its main beneficiaries. The treatment is a proven technique that contributes to increasing patients' oral health. Indeed, the findings could have important repercussions in the promotion of oral health among children, since it implies an increase in the available intervention technology.

It is important to note that this study does not pose any type of risk to any of the participating patients. On the contrary, like any dental intervention technique, this study meets all the requirements for the early and correct identification of children at risk of caries. In these interventions different oral hygiene strategies, healthy dietary habits and preventive measures were implemented, so that the caries disease was controlled and its rate of progression decreased.

Where is the study run from?

University of Murcia Dental Clinic, Hospital General Universitario Morales Meseguer, Murcia (Spain)

When is the study starting and how long is it expected to run for?

February 2016 to December 2018

Who is funding the study?

University of Murcia (Spain)

Who is the main contact?

Andrea Poza Pascual

andrea.poza@ehu.eus

Contact information

Type(s)

Scientific

Contact name

Ms Andrea Poza Pascual

ORCID ID

<http://orcid.org/0000-0001-5718-2288>

Contact details

Tiboli 1, 1º Dcha

Bilbao

Spain

48007

+34 (0)620025288

andrea.poza@ehu.eus

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

POZA

Study information

Scientific Title

Effects of fluoride and calcium phosphate-based varnishes on plaque index and salivary pH, lactic acid, trace elements and bacterial count of children at high risk

Acronym

-

Study objectives

The hypothesis was that the application of the two varnishes applied quarterly for 12 months changes either pH, lactic acid concentrations or levels of trace metals in the saliva of children at high risk of caries

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/05/2017, Ethics Research Committee and the Research Biosecurity Committee of the University of Murcia (University of Murcia: Merced Campus, Calle San Cristo 1, 30001, Murcia, Spain; +34 (0)868 88 3614; comision.etica.investigacion@um.es), ref: CIS: 1499/2017; CBE 50 /2017

Study design

Single-centre controlled randomized clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Caries

Interventions

Participants were randomized to control (placebo), MI Varnish (CPP-ACP with sodium fluoride 5%) or Clinpro White Varnish (FTCP with sodium fluoride 5%) applied every 3 months. Baseline and three-monthly saliva samples were taken for 12 months.

Intervention Type

Other

Primary outcome measure

Measured at baseline, 3, 6, 9 and 12 months:

1. pH measured using a pH test strip (range 4.0–9.0; Code. 1.16996.0001; Reflectoquant™ Merck, Darmstadt, Germany) introduced in an RQflex®10 reflectometer (Merck Millipore, Darmstadt, Germany)
2. Lactic acid concentration measured using a lactic acid test strip (range 1.0-60.0 mg/L; Code. 1.16127.0001; Reflectoquant™ Merck, Darmstadt, Germany) introduced in an RQflex® 10 reflectometer (Merck Millipore, Darmstadt, Germany)
3. Trace elements in saliva (24Mg, 31P, 66Zn, 23Na, 27Al, 39K, 44Ca, 52Cr, 55Mn, 57Fe, 59Co, 63Cu, 75As, 111Cd, 137Ba and 208Pb) measured using mass spectrometry with inductively coupled argon plasma (ICP-MS Agilent 7900; Agilent Technologies Inc.; CA; USA)
4. Plaque index measured using a three-tone discoloring agent (Triplaque, GC, Leuven, Belgium) and Turesky modification of the Quigley-Hein plaque index scale. Additionally, the researchers developed their own Plaque Maturity and Acidity Index (PMAI)
5. Quantitative analysis of bacterial load in saliva samples by qPCR using universal primers on the 16S ribosomal gene with high coverage rate in all bacteria PCR (Polymerase Chain Reaction). DNA extraction performed with the Maxwell AS1290 LEV Blood DNA Kit (Promega Biotech Ibérica S.L, Madrid, Spain). DNA read by fluorimetry on the Prusga Quantus kit with the Quantifluor ONE dsDNA System (Promega Biotech Ibérica S.L, Madrid, Spain)

Measured at baseline and 12 months:

1. 19F measured in saliva using an ion-specific fluoride electrode (Orion 9609 BNWP, Thermo Fisher Scientific Inc. Waltham, USA) coupled to an ion analyzer (Orion EA-940 Thermo Fisher Scientific Inc. Waltham, USA)
2. Caries index using the dmfs/DMFS (decayed, missing and filled teeth surface)

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

10/02/2016

Completion date

31/12/2018

Eligibility

Key inclusion criteria

Children aged 4-12 years attending the Integrated Child Dentistry Clinic of the University of Murcia for checkups or dental treatment who presented a high or extreme risk of caries according to the CAMBRA protocol

Participant type(s)

Patient

Age group

Child

Lower age limit

4 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

58

Total final enrolment

33

Key exclusion criteria

1. Children who had received fluoride varnish or other permanent surface treatment containing fluoride in the previous 6 months
2. Children fitted with orthodontic apparatus
3. Children living in an area with fluoridated drinking water
4. Children with moderate or severe fluorosis or other morphological or anatomical abnormalities of dental development
5. Children with systemic diseases causing physical limitations
6. Children with allergy or proven/suspected sensitivity to milk proteins

Date of first enrolment

01/06/2017

Date of final enrolment

31/12/2018

Locations**Countries of recruitment**

Spain

Study participating centre

University of Murcia Dental Clinic Hospital Morales Meseguer
Av Marqués de los Vélez s/n
Murcia
Spain
30008

Sponsor information

Organisation

University of Murcia

Sponsor details

Calle Campus Universitario, 11
Murcia
Spain
30100
+34 (0)620025288
poza.andrea@gmail.com

Sponsor type

University/education

Website

<http://www.um.es/>

ROR

<https://ror.org/03p3aeb86>

Funder(s)

Funder type

University/education

Funder Name

Universidad de Murcia

Alternative Name(s)

University of Murcia

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Spain

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

26/11/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Andrea Poza Pascual (andrea.poza@ehu.eus) regarding sociodemographic data or measured outcomes (salivary pH, lactic acid, trace elements and bacterial load and plaque index). The results will be available following publication of the study and ending 5 years following article publication. Data will be shared with anyone who wishes to access it for any type of analyses. Proposals should be directed to andrea.poza@ehu.eus and to gain access, anyone requesting access to data will be required to sign a data access agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		26/05/2020	08/06/2020	No	No
Results article		24/09/2021	03/03/2022	Yes	No