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The effect of casein phosphopeptide - amorphous calcium phosphate on saliva

Submission date 05/11/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/11/2022	**Overall study status** Completed	
Last Edited 12/04/2023	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Dental caries (tooth decay) has multiple causes, including dental plaque, which can be controlled with a mixture of different strategies. Increasing the secretion of saliva increases the proportion of calcium and phosphate ions dissolved, reducing demineralization and promoting remineralization, which in turn prevents caries. Casein phosphopeptide - amorphous calcium phosphate (CPP-ACP) has been demonstrated to have anticariogenic activity. Due to the lack of any studies on the effect of pastes containing this substance on saliva, the aim of this study is to investigate its effectiveness in increasing the proportion of calcium in saliva and its impact on the pH and salivary flow rate, and the tooth remineralization process in children.

Who can participate?
Children aged 6-8 years old

What does the study involve?
Participants will be asked to apply GC tooth mousse (containing CPP-ACP) or placebo (dummy) mousse in order to study the changes in saliva pH, salivary flow rate and calcium concentration in saliva.

What are the possible benefits and risks of participating?
The GC tooth mousse may help with the remineralization process. There are no risks involved.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
September 2021 to April 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Muaaz Alkhouli, muaaz.alkhouli@outlook.com

Contact information

Type(s)
Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

2090

Study information

Scientific Title
The effect of casein phosphopeptide - amorphous calcium phosphate on salivary flow rate, salivary pH and salivary calcium concentration in children

Acronym
CPP-ACP

Study objectives
1. Casein phosphopeptide - amorphous calcium phosphate (CPP-ACP) causes an increased salivary flow rate compared with a placebo
2. CPP-ACP results in a higher pH of saliva compared with a placebo
3. CPP-ACP increases the calcium concentration of saliva more than the placebo does

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2021, ethics scientific committee at Damascus University (Mazzeh Street, Damascus, Syria; +963 (0)9933490577; drsalloum74@hotmail.com), ref: 2090

Study design
Interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Remineralization capacity of CPP-ACP

Interventions
Participants will be allocated equally into two groups: Group 1 (intervention) receive GC Tooth Mousse (CPP-ACP) and Group 2 (control) receive a placebo mousse.

A random allocation list will be carried out using the website https://www.randomlists.com/, all of the participants will be numbered from 1 - 50 in order to allocate them randomly into the two study groups.

Saliva samples are taken from the participants before the application, after the application directly, after half an hour and after an hour. the pH of the collected samples, salivary flow rate and calcium concentration are tested.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Casein Phosphopeptide-Amorphous Calcium Phosphate (CPP-ACP), GC tooth mousse

Primary outcome measure
Measured at T0: before the application (baseline); T1: directly after the application ; T2: after half an hour; T3: after 1 hour:
1. pH of saliva measured using pH test strips (Whatman® Panpeha™ pH indicator strips)
2. Salivary flow rate measured by calculating the amount of saliva which will be collected in tubes and dividing it into five to see the amount of saliva secreted per minute (ml/d)

Secondary outcome measures
Calcium concentration of saliva measured using Calein as an indicator, ethylenediaminetetra-acetate (EDTA) as a Ca-complexing agent, and a standard Ca solution to set up the calibration series; measured at T0: before the application (baseline); T1: directly after the application ; T2: after half an hour; T3: after 1 hour.

Overall study start date
17/09/2021

Completion date
04/04/2022

Eligibility

Key inclusion criteria
1. Good oral hygiene
2. Participants not be taking antibiotics or any kind of medications that can affect the flow rate of saliva
3. Does not suffer from an allergy to milk protein confirmed or suspected and/or the presence of the sensitivity of benzoate (preservative)

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Taking antibiotics or drugs that may affect the salivary flow rate
2. The existence of diseases that may affect the flow rate of saliva or a combination such as diabetes
3. Sensitivity to milk protein confirmed or suspected and/or the presence of the sensitivity of benzoate (preservative)

Date of first enrolment
01/12/2021

Date of final enrolment
02/03/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh Street
Damascus
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
04/04/2023

Individual participant data (IPD) sharing plan
The original data, along with the codebook and analysis scripts, will be stored at the Damascus University repository. The data will consist of csv sheets with the data of the patients and R analysis scripts. The dataset will be called dataset and the dataset generated by the research,

including also preprints and technical reports, will be called dataverse. The dataverse corresponding to this investigation will receive a digital object identifier (DOI). The citation has seven components. Five are human-readable: the author(s), title, year, data repository (or distributor), and version number. Two components are machine-readable: the DOI and the universal numeric fingerprint (UNF). The data generated will be de-identified using R's randomizeR package, removing all personal information. The naming convention for the archives will be date in yyyymmdd-version-identifier.extension format. The use of spaces will be avoided, being replaced by -. The original anonymized data will be published in the Mendeley data repository with restricted access once the data cleaning and exploratory analysis stage is completed. The data will be made public at the time of sending the final report to a peer-reviewed journal, with its DOI corresponding to the data associated with the research. The data will be embargoed until the final report is accepted, at which time it will become publicly available. No access restrictions will be applied to the data once the final project report has been accepted.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Salivary pH and salivary flow results	11/04/2023	12/04/2023	Yes	No