

The effect of casein phosphopeptide - amorphous calcium phosphate on saliva

Submission date 05/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/04/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 (Mazze 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 Calcine as an indicator, ethylenediaminetetraacetate (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**

Mazze Street

Damascus

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Sponsor information**Organisation**

Damascus University

Sponsor details

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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 yyyyymmdd-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