

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effect of CPP-ACP and CPP-ACPF pastes on dental plaque pH changes after sugar consumption.

Protocol summary

Summary

The aim of the study is to compare two pastes containing CPP-ACP and CPP-ACPF on dental plaque pH changes following sugar consumption. This study is designed as a randomized, double-blind trial. Forty 12-14 year old students are recruited and ordered not to eat or brush at least 2 hours prior to the intervention. After obtaining a dental plaque sample from the distal aspect of the first permanent molar for pH measurement, they will be given a %10 sucrose solution and after 10 minutes, another sample is taken for pH measurement. In the next stage, the students are randomly allocated to two study groups. The operator blindly applies a CPP-ACP paste to the teeth and a CPP-ACPF paste to the second. Plaque samples for pH measurements are collected again after 30 and 60 minutes and after 24, 48, and 96 hours. These recordings shall be statistically analyzed with repeated measures ANOVA tests.

General information

Acronym

CPP-ACP :Casein Phospho Peptide- Amorphous Calcium Phosphate
CPP-ACPF :Casein Phospho Peptide- A

IRCT registration information

IRCT registration number: **IRCT2012113010086N2**
Registration date: **2013-02-18, 1391/11/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-18, 1391/11/30

Registrant information

Name

Haleh Heshmat

Name of organization / entity

Islamic Azad Dental University, Tehran

Country

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+98 21 8887 8135

Email address

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Recruitment status

Recruitment complete

Funding source

Islamic Azad Dental University

Expected recruitment start date

2013-02-23, 1391/12/05

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of CPP-ACP and CPP-ACPF pastes on dental plaque pH changes after sugar consumption.

Public title

Comparing the effect of two different pastes on dental plaque pH changes and caries prevention after sugar consumption.

Purpose

Prevention

Inclusion/Exclusion criteria

40 male students with an average oral hygiene and plaque index of at least 10% which have neither eaten nor brushed for at least 2 hours prior to obtaining first plaque samples of the intervention.

Age

From **12 years** old to **14 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block randomization with a block size of 4

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic azad university of dentistry, Tehran

Street address

No. 4, Neyestan 10, Pasdaran, Tehran

City

Tehran

Postal code

Approval date

2011-12-11, 1390/09/20

Ethics committee reference number

پ/768/د

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

pH of dental plaque

Timepoint

0, 10, 30, 60 minutes and 24, 48, 96 hours after

Method of measurement

Diagnostic pH plaque kit

Secondary outcomes

empty

Intervention groups

1

Description

A paste containing casein phosphopeptide amorphous calcium phosphate is applied on the tooth surface for 5 minutes after the patient has used a 10% sucrose solution, followed by pH measurement

Category

Prevention

2

Description

A paste containing casein phosphopeptide amorphous calcium phosphate and 900ppm fluoride is applied on the tooth surface for 5 minutes after the patient has used a 10% sucrose solution, followed by pH measurement

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi education center

Full name of responsible person

Hadi Abdian- Dentist

Street address

Shahid Rajaie ave, Basij avenue, Chaharmahal ave

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor of research center of Islamic Azad Dental University, Tehran

Full name of responsible person

Arash Azizi

Street address

Neyestan 10th, Pasdaran ave, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Chancellor of research center of islamic azad dental university,Tehran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad Dental University,Tehran

Full name of responsible person

Haleh heshmat

Position

Profissional Assistance

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty