

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

Iran (Islamic Republic of)

###### Phone

+98 21 8887 8135

###### Email address

h\_heshmat@dentaliau.ac.ir

###### 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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**Fax**

**Email**

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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*