

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparative evaluation of the effects of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) and Xylitol-containing chewing gum on salivary flow rate, pH and concentration of calcium and phosphate

#### Protocol summary

##### Study aim

The effect of chewing gum containing CPP-ACP and xylitol on the volume and pH of saliva and the amount of calcium and phosphate ions present in saliva

##### Design

Three arm parallel group randomised trial, Randomised

##### Settings and conduct

This study is done at Yazd Dental School. In this study, after grouping two samples of saliva will be taken (before and after chewing gum). People should chew gum for 5 minutes

##### Participants/Inclusion and exclusion criteria

60 dental students with the following conditions:  
Complete health systemically Not having a special diet  
No evidence of dry mouth Not taking antibiotics and antacids two weeks before the test No use of orthodontic plaque and prosthesis No smoking, no pregnancy, no periodontal disease, no active caries

##### Intervention groups

Group 1: A piece of gum containing ACP-CPP with peppermint flavor  
Group 2: One piece of Xylitol gum  
Group 3: A piece of paraffin will be given

##### Main outcome variables

salivary flow rate, pH and concentration of calcium and phosphate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140601017935N8**

Registration date: **2019-12-14, 1398/09/23**

Registration timing: **prospective**

Last update: **2019-12-14, 1398/09/23**

Update count: **0**

##### Registration date

2019-12-14, 1398/09/23

##### Registrant information

###### Name

Zahra Bahrololoomi

###### Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1624 0691

###### Email address

zbahrololoom@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-21, 1398/09/30

##### Expected recruitment end date

2020-01-19, 1398/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of the effects of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) and Xylitol-containing chewing gum on salivary flow rate, pH and concentration of calcium and phosphate

##### Public title

Comparative evaluation of the effects of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) and Xylitol-containing chewing gum on salivary

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

تعداد 60 نفر از دانشجویان دندان پزشکی دارای سلامت کامل از لحاظ سیستمیک

##### Exclusion criteria:

داشتن رژیم غذایی خاص افراد مبتلا به خشکی دهان تشخیص داده نشده افرادی که آنتی بیوتیک و دارو های آنتی اسید دو هفته قبل از شروع آزمایش مصرف کردند استفاده از پلاک ارتودنسی و پروتز استعمال سیگار بارداری داشتن بیماری پرپودنتال افرادی که پوسیدگی فعال نداشته باشند

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: 60

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomization personal, using the random number table

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The researcher does not know in which group each person belongs, and the outcome assessor is unaware of which group the samples were in.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences

##### Street address

Central Organization for Shahid Sadoughi University of Medical Sciences, Bahonar S., Yazd

##### City

Yazd

#### Province

Yazd

#### Postal code

8916978477

#### Approval date

2019-09-23, 1398/07/01

#### Ethics committee reference number

IR.SSU.REC.1398.096

## Health conditions studied

### 1

#### Description of health condition studied

chewing gum

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

chewing gum

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

changes in salivary flow rate, pH and concentration of calcium and phosphate

#### Timepoint

Before the intervention, immediately after the intervention

#### Method of measurement

Salivary volume will be measured by calibrated pipette, salivary pH using a calibrated digital pH meter, salivary calcium spectrophotometric method, salivary phosphate will be measured spectrophotometric method.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:First Intervention group : First,They will brush twice daily for 3 weeks with a toothbrush(Medical) and toothpaste(Nasim). On the sampling day they will not eat anything for 2 hours and then give them a chewing gum CCP-ACP (Trident Recaldent with The peppermint flavor) is given and after 5 minutes of chewing, the saliva is collected

#### Category

Other

## 2

### Description

Intervention group: : second Intervention group :  
First,They will brush twice daily for 3 weeks with a toothbrush(Medical) and toothpaste(Nasim). On the sampling day they will not eat anything for 2 hours and then give them a chewing gum Xylitol (Trident) with The peppermint flavor is given and after 5 minutes of chewing, the saliva is collected

### Category

Other

## 3

### Description

Control group: First,They will brush twice daily for 3 weeks with a toothbrush(Medical) and toothpaste(Nasim). On the sampling day they will not eat anything for 2 hours and then give them a piece of paraffin is given and after 5 minutes of chewing, the saliva is collected

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

دانشکده دندانپزشکی دانشگاه علوم پزشکی شهید صدوقی یزد

##### Full name of responsible person

Arezoo Ghotbzade

##### Street address

Yazd, Dahe Fajr Blvd, Faculty of Dentistry

##### City

Yazd

##### Province

Yazd

##### Postal code

8914881167

##### Phone

+98 35 3625 5881

##### Fax

+98 35 3625 5881

##### Email

Arezoo.ghotbzade@yahoo.com

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

خانم خضری

##### Street address

Yazd, Dahe Fajr Blvd, Faculty of Dentistry

##### City

Yazd

##### Province

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##### Postal code

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##### Phone

+98 35 3625 5881

##### Fax

##### Email

pajoheshdentyazd@gmail.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Yazd University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Arezoo Ghotbzade

##### Position

Dental student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

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##### Province

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arezoo.ghotbzade@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Dr. Zahra Bahrololoomi

**Position**

Associate professor of Pediatric Dentistry

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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zbahrololoom@ssu.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Arezoo Ghotbzade

**Position**

Dental student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Email**

Arezoo.ghotbzade@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available