Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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 پریودنتال 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
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Street address
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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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Person responsible for updating data

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Position
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Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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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