

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of casein phosphopeptide-amorphous calcium phosphate(CPP-ACP) and Xylitol Chewing gums and probiotic yogurt on streptococcus mutans and microbial dental plaque

Protocol summary

Summary

The propose of this study is to determine the effect of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) and Xylitol Chewing gums and probiotic yogurt on streptococcus mutans and microbial dental plaque. In this randomized clinical trials 112 students of dentistry who have 22 teeth and good oral hygiene are attended. Exclusion criteria: Systemic diseases that affect dental and periodontal conditions; Orthodontic appliance; active dental caries; choronic mucositis; chronic antibiotic usage; antibacterial mouth rinse consumption; drugs consumption which affect saliva flow rate; radio therapy history This 112 samples are randomly divided into 4 groups Group 1: chewing 20 minutes Xylitol gum 3 times a day for 30 days. Group 2: chewing 20 minutes CPP-ACP gum 3 times a day for 30 days. Group 3: 200 grams probiotic yogurt once a day for 30 days Group 4: 5 cc chlorhexidine mouth rinse every night for 15 days at base line and before intervention plaque index is recorded and saliva of samples are taken and will be assessed for mutans count. Then after 15, 30 days of intervention, again plaque index and mutans saliva count will be recorded. For group 4 just after 15 days the plaque index and mutans saliva count will be recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100730193N1**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Iman Parisay

Name of organization / entity

Mashhad University of Medical Sciences-Mashhad
Dental Faculty

Country

Iran (Islamic Republic of)

Phone

+98 51 3608 6977

Email address

parisayi@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Mashhad University of Medical
Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of casein phosphopeptide-amorphous calcium phosphate(CPP-ACP) and Xylitol Chewing gums and probiotic yogurt on streptococcus mutans and microbial dental plaque

Public title

Comparison of the effect of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) and Xylitol Chewing gums and probiotic yogurt on streptococcus

mutans and microbial dental plaque

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Dental students; have 22 teeth; good oral hygiene Exclusion criteria: systemic diseases that affect dental and periodontal conditions; orthodontic appliance; active dental caries; chronic mucositis; chronic antibiotic usage; antibacterial mouth rinse consumption; drugs consumption which affect saliva flow rate; radio therapy history

Age

From **20 years** old to **27 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomization table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences Ethics Committee

Street address

Mashhad Dental Faculty-Vakil Abbad Blvd

City

Mashhad

Postal code

Approval date

2017-02-08, 1395/11/20

Ethics committee reference number

IR.mums.sd.REC.1394.199

Health conditions studied

1

Description of health condition studied

dental Plaque-Streptococcus mutans counts

ICD-10 code

Z01.2-k03.

ICD-10 code description

DENTAL EXAMINATION-Deposites on tooth

Primary outcomes

1

Description

human smutans streptococci counts in salive-Dental Plaque

Timepoint

base line -15 day-30 day

Method of measurement

Micobial culture-plaque index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: chewing 20 minutes Xylitol gum 3 times a day for 30 days.

Category

Treatment - Drugs

2

Description

Intervention group 2: chewing 20 minutes CPP-ACP gum 3 times a day for 30 days

Category

Treatment - Drugs

3

Description

Intervention group 3:200 grams probiotic yogurt once a day for 30 days

Category

Treatment - Drugs

4

Description

Control group 4: 5 cc chlorhexidine mouth rinse every night for 15 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental Faculty
Full name of responsible person
Dr.Iman Parisay
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Mashhad Dental Faculty-Vakil Abbad BLVD
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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Vice chancellor of Mashhad University of
Medical Sciences
Full name of responsible person
Dr.Mohsen Tafaghodi
Street address
Research Vice chancellor of Mashhad University of
Medical Sciences -Daneshgah Street
City
Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice chancellor of Mashhad University of
Medical Sciences

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
Mashhad Dental Faculty
Full name of responsible person
Dr.Iman Parisay
Position
Associate Professor of pediatric dentistry department
Other areas of specialty/work
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Person responsible for updating data

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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

