

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of two types of chewing gum containing casein phosphopeptide-amorphous calcium phosphate and xylitol on amounts of streptococcus mutans.

Protocol summary

Summary

After approval of the project and coordinate with the laboratory Shyahid Beheshti Dental School, 60 students are selected on the basis of having the condition. Among the conditions for entry into the study sample; tooth decay or caries-free and have no periodontal disease and other gum of any kind should not be used during the study. After signing the informed consent, which was approved by the ethics committee, students will be divided into two groups of 30; then saliva sent to the laboratory and measured the salivary mutans streptococci, then randomly assigned to groups of type sag and more homogeneous stratified blocks simultaneously group A and group B xylitol chewing gum and Recaldent chewing gum, 3 times a day (every time 20 minutes) for 3 weeks. After the specified time period (3 weeks), saliva samples were collected again and are sent to the shahid Beheshti laboratory immediately and change in salivary streptococcus mutans of each group are measured, recorded and compared.

General information

Acronym

E Ch. g CPP-ACP &Z on SM

IRCT registration information

IRCT registration number: **IRCT2014063018296N1**

Registration date: **2014-08-02, 1393/05/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-02, 1393/05/11

Registrant information

Name

Yosra Khateri Zadeh

Name of organization / entity

International Branch of Shahid Beheshti University
Dental School

Country

Iran (Islamic Republic of)

Phone

Email address

yosra_khaterizadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

The International branch of shahid beheshti university of
medical sciences dental school

Expected recruitment start date

2014-08-02, 1393/05/11

Expected recruitment end date

2014-08-07, 1393/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of two types of chewing gum containing casein phosphopeptide-amorphous calcium phosphate and xylitol on amounts of streptococcus mutans.

Public title

The effect of two types of chewing gum containing CPP - ACP and xylitol on caries-causing bacteria in the mouth.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. No tooth decay or caries. 2. Lack of systemic antibiotics during the last 3 months. 3. Topical

fluoride therapy during the 4-week period before baseline were not include. 4. No signs of any gingivitis or periodontal diseases. 5. Do not have habitual use of dairy xylitol or recalcident chewing gum. 6. Do not have smoking habit. 7. Have no history of systemic disease. Exclusion criterion: patients will to be excluded from the study.

Age

From **20 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

International Branch of Shahid Beheshti University of Medical Sciences, Dental School

Street address

19 shahid abbaspour St, vali-asr Ave, Tehran-Iran

City

Tehran

Postal code

141553693

Approval date

2014-07-22, 1393/04/31

Ethics committee reference number

1000/289

Health conditions studied**1****Description of health condition studied**

Initial caries & salivary mutans streptococcus

ICD-10 code

K02.0

ICD-10 code description

Caries limited to enamel

Primary outcomes**1****Description**

Streptococcus mutans

Timepoint

Baseline salivary streptococcus mutans and after chewing gum salivary SM is measured.

Method of measurement

Saliva is collected by sterile micro tubes.

Secondary outcomes**1****Description**

Side effects of CPP-ACP has been not reported but people who have allergies to milk not to use the gum.

Timepoint

During of study

Method of measurement

If see any signs.

Intervention groups**1****Description**

Group II: chewing gum containing CPP-ACP. After selecting individuals for entry into the study and informed consent and informed them orally A 30-member is asked daily after breakfast and after lunch and dinner take away their toothbrushes every meal a grain of chewing gum for 20 minutes and then take away the gum. These Mtah is 3 weeks. (Gum weight = 47.6 grams)

Category

Prevention

2**Description**

Group I: chewing gum containing xylitol. After selecting individuals for entry into the study and informed consent and informed them orally A 30-member is asked daily after breakfast and after lunch and dinner take away their toothbrushes every meal a grain of chewing gum for 20 minutes and then take away the gum. These Mtah is 3 weeks. (Gum weight = 31 grams)

Category

Prevention

Recruitment centers**1****Recruitment center**

Name of recruitment center

International Branch of Shahid Beheshti University of
Medical Sciences, Dental School

Full name of responsible person

Yosra Khaterizadeh

Street address

168 jamshid alley, Southern jamalzadeh St., azadi
Ave., tehran-iran

City

Tehran

1454663349

Phone

+98 21 6691 7171

Fax

Email

Yosra_khaterizadeh@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International branch of shahid beheshti university of
medical sciences & health services dental s

Full name of responsible person

Dr. Hamid Soori

Street address

19 shahid abbasspour St., vali-asr Ave., tehran-iran

City

Tehran

Grant name

123808

Grant code / Reference number

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

Yes

Title of funding source

International branch of shahid beheshti university of
medical sciences & health services dental s

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

International Branch of Shahid Beheshti University of
Medical Sciences, Dental School

Full name of responsible person

Yosra Khaterizadeh

Position

Dentist

Other areas of specialty/work

Street address

Dental Clinic, Shahid Beheshti Center, South
Jamalzadeh st., Azadi Ave

City

Tehran

Postal code

Person responsible for scientific inquiries

Contact

Name of organization / entity

International Branch of Shahid Beheshti University of
Medical Sciences, Dental School

Full name of responsible person

Yosra Khaterizadeh

Position

Dentist

Other areas of specialty/work

Street address

Dental Clinic, Shahid Beheshti Center, South
Jamalzadeh st., Azadi Ave.

City

Tehran

Postal code

1454663349

Phone

+98 21 6691 7171

Fax

Email

Yosra_khaterizadeh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

International Branch of Shahid Beheshti University of
Medical Sciences, Dental School

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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