Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of two typs 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 typs 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 recaldent 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 streptoccus

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

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

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

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Person responsible for scientific inquiries

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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

Data Dictionary

empty