Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of pure mastic gums, mastic gums enriched with probiotics and mastic gums with xylitol on the number of Mutans streptococci, Lactobacilli and PH of saliva

Protocol summary

Summary

The aim of the study is to investigate the effect of pure mastic gums, mastic gums enriched with probiotics and xylitol added mastic gums on the number of Mutans streptococci, Lactobacilli and PH of saliva. 42 healthy volunteer dental students (20-30years old) are asked to brush their teeth using a similar toothbrush and toothpaste for two weeks. Afterwards the saliva samples will be collected and the Mutans streptococci count, Lactobacilli count and the PH of saliva will be recorded. The subjects will be randomly assigned to three equally sized groups, who chew one of three types of mastic gums (probiotic enriched, xylitol added or pure mastic gum) three times daily,5 minutes each time, for three weeks. Unstimulated saliva will be collected again for each person after mastic gums consumption period. The numbers of mutans streptococci and Lactobacilli and also the PH of each saliva sample will be measured. The data will be analyzed using statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110267910N1**
Registration date: **2012-01-15, 1390/10/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-01-15, 1390/10/25

Registrant information

Name

Mina Biria

Name of organization / entity

Shaheed Beheshti Dental School

Country

Iran (Islamic Republic of)

Phone

+98 21 2990 2304

Email address

dr.biriam@dent.sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti dental school

Expected recruitment start date

2012-01-19, 1390/10/29

Expected recruitment end date

2012-01-26, 1390/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of pure mastic gums, mastic gums enriched with probiotics and mastic gums with xylitol on the number of Mutans streptococci, Lactobacilli and PH of saliva

Public title

The effects of pure mastic gums, mastic gums enriched with probiotics and mastic gums with xylitol on cariogenic microflora and PH of saliva

Purpose

Prevention

Inclusion/Exclusion criteria

Including criteria: 1) Dental students with the mean age of 25 years old; 2) Teeth brushing twice a day using

fluoridated toothpaste. Excluding criteria: 1) history of systemic disease; 2) habitual use of xylitol or probiotic containing products; 3) previous use of systemic antibiotics and fluoride products at least four weeks before starting the study; 4) Existence of untreated carious teeth, gingivitis and periodontal diseases.

Age
From **20 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee, Shahid Beheshti University of Medical Sciences

Street address
Daneshjoo blvd, Evin

City
Tehran

Postal code

Approval date
2010-06-12, 1389/03/22

Ethics committee reference number
101

Health conditions studied

1

Description of health condition studied
Caries

ICD-10 code
B99

ICD-10 code description
Other and unspecified infectious diseases

Primary outcomes

1

Description
Lactobacilli count of saliva

Timepoint
before and three weeks after intervention

Method of measurement
colony count(cfu)

2

Description
PH of saliva

Timepoint
before and three weeks after intervention

Method of measurement
numerical value according to the reading of PH meter

3

Description
Mutans Streptococci count of saliva

Timepoint
before and three weeks after intervention

Method of measurement
colony count(cfu)

Secondary outcomes

empty

Intervention groups

1

Description
chewing xylitol containing mastic gum, three times a day after meal, 5 minutes each time

Category
Prevention

2

Description
chewing pure mastic gum, three times a day after meal, 5 minutes each time

Category
Prevention

3

Description
chewing probiotic enriched mastic gum, three times a day after meal, 5 minutes each time

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Dental School

Full name of responsible person
Dr. Mina Biria, Dr. Gita Eslami

Street address
Pediatric dentistry Department, Shahid Beheshti Dental School, Daneshjoo blvd, Evin

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Beheshti Dental School

Full name of responsible person
Mr. Farhadi, Dr. Vahid Dastgerdi

Street address
Pediatric Dentistry Department, Shahid Beheshti Dental School, Daneshjoo blvd., Evin

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Shahid Beheshti Dental School

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
Shahid Beheshti Dental School

Full name of responsible person
Dr. Mina Biria

Position
Board of pediatric Dentistry-Associate professor

Other areas of specialty/work

Street address
Pediatric dentistry department, Shahid Beheshti dental school, Daneshjoo blvd., Evin

City
Tehran

Postal code

Phone
+98 21 2990 2304

Fax
+98 21 8851 3649

Email
dr.biriam@dent.sbmu.ac.ir , dr.biriam@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti Dental School

Full name of responsible person
Dr. Mina Biria

Position
Board of Pediatric Dentistry-Associate professor

Other areas of specialty/work

Street address
Pediatric Dentistry Department, Shahid Beheshti Dental School, Daneshjoo Blvd., Evin

City
Tehran

Postal code

Phone
+98 21 2990 2304

Fax
+98 88513649

Email
dr.biriam@dent.sbmu.ac.ir , dr.biriam@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Pediatric Dentistry Departmant, Shahid Beheshti Dental School

Full name of responsible person
Dr. Mina Biria

Position
Associate Professor

Other areas of specialty/work

Street address
Pediatric Dentistry Departmant, Shahid Beheshti Dental School, Daneshjoo blvd., Evin

City
Tehran

Postal code
1533673513

Phone
+98 21 8874 7022

Fax
+98 21 8851 3649

Email
dr.biriam@dent.sbmu.ac.ir

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