

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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.sbm.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

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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**

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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