

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial of the effect of probiotic yogurt mouthwash on salivary pH in orthodontic patient in sari dentistry school clinic

Protocol summary

Summary

This single-blind clinical trial aims to investigate the effect of probiotic yogurt mouthwash on salivary pH of 40 patients 14-17 years old with both jaws fixed orthodontic appliances. Exclusion criteria includes tooth decay, systemic and gum diseases, the use of steroids and other drugs, smoking and pregnancy. Patients are randomly divided into two groups with table of random numbers. Yogurts are given in similar packages to the patients. During the first period, patients in both groups will not use yogurt for a week. The intervention group receives 20 mL probiotic yogurt (20.000.000 colony/gram Lactobacillus acidophilus and Bifidobacterium lactis) and the control groups receives 20 mL nonprobiotic yogurt after brushing and flossing 2 times daily for 2 weeks for one minute mouthwash, and then avoid mouth washing, eating and drinking for one hour and then wash their mouth. The third period is 2 weeks rest and the patients avoid the consumption of yogurt. In the fourth period, patients in the intervention group receive nonprobiotic yogurt and the control group patients receive probiotic yogurt twice daily for 2 weeks. At the beginning and end of 2nd and 4th period, salivary pH of all patients are measured by labtron ph meter made by Labtron co. Iran. At 10-11 am, unstimulated saliva samples are collected. pH 5 to 5.8 is very acidic, 6 to 6.6 relatively acidic and pH of 6.8 to 7.8 indicates healthy saliva.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040533236N1**
Registration date: **2017-07-25, 1396/05/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

Nafiseh Zarenejad

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

nzarenejad@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology of Mazandaran University of Medical Sciences

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of probiotic yogurt mouthwash on salivary pH in orthodontic patient in sari dentistry school clinic

Public title

The effect of probiotic yogurt mouthwash on salivary pH

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 14-17 years; fixed orthodontic treatment of jaw distance of at least 3 months of treatment Exclusion criteria: Dental decay; systemic diseases; Any disease of the gums and teeth; Systemic corticosteroid and other medications including antibiotics; Chlorhexidine mouthwash; Xylitol gum chewing during the past 4 weeks; smoking; Pregnancy; OCP

Age

From **14 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology,
Moallem square, Sari, Iran

City

Sari

Postal code

4815838447

Approval date

2016-10-25, 1395/08/04

Ethics committee reference number

IR.MAZUMS.REC.95.2122

Health conditions studied

1

Description of health condition studied

Fixed orthodontic for teeth

ICD-10 code

Z46.4

ICD-10 code description

Fitting and adjustment of orthodontic device

Primary outcomes

1

Description

Salivary pH

Timepoint

Start of treatment, at the end of 1st, 2nd, 3rd and 4th course

Method of measurement

pH meter

Secondary outcomes

empty

Intervention groups

1

Description

The control group receives 20 mL nonprobiotic yogurt mouthwash twice daily for 2 weeks.

Category

Placebo

2

Description

The intervention group receives 20 mL probiotic yogurt (20.000.000 colony/gram Lactobacillus acidophilus and Bifidobacterium lactis) after brushing and flossing 2 times daily for 2 weeks for one minute mouthwash

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran University of Medical Sciences

Full name of responsible person

Nafiseh Zarenejad

Street address

Next to Tooba Clinic, Faculty of Dentistry, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmadali Enayati

Street address

Vice chancellor for research of Mazandaran University of Medical Sciences, Moallem Square, Sari

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Sari

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 of Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Nafiseh Zarenejad

Position

Assistant Professor

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Assistant Professor, Tooth Restoration Specialist

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Fax**Email****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*