

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

A clinical trial to compare the effectiveness of probiotics pills with fluoride mouthwash on microbial population in saliva in fixed orthodontic patients

Protocol summary

Study aim

To compare the effectiveness of probiotics pills with fluoride mouthwash on microbial population in saliva in fixed orthodontic patients

Design

Totally, 75 patients whose undergoing fixed orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran. In this double-blind, controlled clinical trial, the patients are assigned into parallel groups using simple sampling methods.

Settings and conduct

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection and clinical care is blind to group allocation and the type of drugs. Patients will receive Lacto Gum biodegradable, placebo and fluoride mouthwash for 3 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 17-18 years; no history of systemic disease; nonuse of antibiotic and probiotic drugs; The patient is in the middle of the spectrum regarding caries risk, and not high caries risk is recommended. In addition, the individual should have good oral hygiene. Exclusion criteria: Dentinogenesis imperfect; amelogenesis imperfect; having specific metabolic diseases; bulimia nervosa; anorexia nervosa; having probiotics drug intolerance.

Intervention groups

The intervention group will receive Lacto Gum biodegradable sucker pills containing Lactobacillus salivarius produced by Biology Fermentation Company for 3 weeks. Control group one will receive sucker pills of placebo without Lactobacillus salivarius for 3 weeks. Control group two will receive fluoride mouthwash for 3

weeks.

Main outcome variables

Evaluation and comparison of the buffering power of the saliva, Streptococcus mutans and Lactobacillus population in between groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200203046363N1**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **prospective**

Last update: **2020-03-02, 1398/12/12**

Update count: **0**

Registration date

2020-03-02, 1398/12/12

Registrant information

Name

Amirreza Faraji Eraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 1674

Email address

farajiar931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of probiotics pills with fluoride mouthwash on microbial population in saliva in fixed orthodontic patients

Public title

The effectiveness of probiotics pills on microbial population in orthodontic patient

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 17-18 years No history of systemic disease
Nonuse of antibiotic and probiotic drugs The patient is in the middle of the spectrum regarding caries risk, and not high caries risk is recommended. In addition, the individual should have good oral hygiene

Exclusion criteria:

Dentinogenesis imperfect Amelogenesis imperfect
Having specific metabolic diseases Bulimia nervosa
Anorexia nervosa Having probiotics drug intolerance

AgeFrom **14 years** old to **18 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample sizeTarget sample size: **75****Randomization (investigator's opinion)**

Randomized

Randomization description

The subjects will be randomly assigned into three groups of 25 patients with blocks of 2, 4, and 6 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sampling using a statistical analysis system (SAS), computer software. Sequentially numbered sealed opaque envelopes will be used to conceal the sequencing. Accordingly, the participants were given codes and assigned into the intervention and two control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection and clinical care are blind to group

allocation and the type of drugs.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.116

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

Orthodontic

ICD-10 code

Z46.5

ICD-10 code description

Fitting and adjustment of ileostomy and other intestinal appliances

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

Buffering power of the saliva

Timepoint

Before and 3 weeks after the intervention

Method of measurement

PH meter device

2**Description**

Streptococcus mutans population

Timepoint

Before and 3 weeks after the intervention
Method of measurement
Microbial counting

3

Description

Lactobacillus population

Timepoint

Before and 3 weeks after the intervention

Method of measurement

Microbial counting

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive Lacto Gum biodegradable sucker pills containing Lactobacillus salivarius produced by Biology Fermentation Company for 3 weeks.

Category

Prevention

2

Description

Control group one will receive sucker pills of placebo without Lactobacillus salivarius produced by Biology Fermentation Company for 3 weeks.

Category

Prevention

3

Description

Control group two will receive fluoride mouthwash for 3 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Amirreza Faraji Eraghi

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

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9177948959

Phone

+98 51 3883 2300

Email

farajiar931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
Street

City

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9138813944

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+98 51 3841 1538

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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amirreza Faraji Eraghi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

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Position

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome or the like can be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working at science centers and universities.

Under which criteria data/document could be used

Our data will be available for scholars working at science centers and universities.

From where data/document is obtainable

Amirreza Faraji Eraghi provides the data analysis to the applicants via email: farajiar931@mums.ac.ir

What processes are involved for a request to access data/document

Applicants can respond to the email of the respondent and receive a response within a week.

Comments