Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of clinical effects of two probiotic products, Lactogum & ParsiLact-LA on oral health of patients treated with removable and fixed orthodontic appliances

Protocol summary

Study aim
Evaluation and comparison of clinical effects of two probiotic products, Lactogum & ParsiLact-LA on oral health of orthodontic patients

Design
A controlled randomized clinical trial, double blind, parallel group design of 60 patients. Block randomization will be performed by random number table.

Settings and conduct
The study will be conducted at Isfahan Dental School. 60 orthodontic patients will randomly be divided into 2 intervention groups and 2 control groups and effects of probiotic consumption on BOP, GI, PI and PH saliva will be evaluated. In the present study, research team members and statistical analyzer will be blinded, by coding system.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients treated with removable and fixed orthodontic appliances of both jaws. Exclusion criteria: any Physical, mental, physiologic & anatomic conditions preventing the intervention.

Intervention groups
In the present study, there are four intervention groups. Two groups will receive probiotics (group A: Lactogum which contains Streptococcus salivarius & group B: ParsiLact-LA which contains Lactobacillus acidophilus) and two groups will receive placebo (which are similar to probiotics in all respects).

Main outcome variables
The score of BOP, GI, PI and PH saliva

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210821052241N1**
Registration date: **2021-10-20, 1400/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-20, 1400/07/28**
Update count: **0**

Registration date
2021-10-20, 1400/07/28

Registrant information

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Saeid Sadeghian
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of clinical effects of two probiotic products, Lactogum & ParsiLact-LA on oral health of patients treated with removable and fixed orthodontic appliances

Public title

Clinical effects of Lactogum and ParsiLact-LA on oral health

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients planned for removable functional orthodontic appliances or full arch both jaws fixed orthodontic appliance therapy. Good general health. Good oral health (have a dental history that includes brushing at least once a day). Be willing and able to comply with the trial regime. To have normal tooth anatomy, oral mucosa and periodontal status.

Exclusion criteria:

Inability to obtain informed consent. Presence of allergies, food sensitivities or food intolerance. Any congenital syndromes of the head and neck. Medical contraindications such as heart conditions or Gastrointestinal disorders. Any state or diseases necessitating taking immunosuppressants or antibiotics or any medication chronically prior to the procedures. Any special physical or mental needs that would compromise patient cooperation. History of surgery within the past year or planned to have a surgery in the next 90 days. Severe fever, nausea, vomiting, bloody Diarrhea or severe abdominal pain within the past 1 month. Chronic use of probiotics or food supplements of any kind and use of antibiotics, steroids, hormones, oral prophylaxis or anti-microbial mouth wash or tooth paste within 1 month before the start of the study. Use of products containing xylitol and fluoride or other anti cariogenic products. Poor compliance with oral hygiene regimens; poor periodontal health(presence of calculus and/or periodontal pocket); extensive dental restorations or uncontrolled caries activity. Pregnancy. Smoking.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, block randomization with a 1: 1 allocation ratio using a random number table and by someone outside the research team will be used. For this purpose we will have 6 blocks (ABC - ACB - BAC - BCA - CAB - CBA). Each block will be randomly assigned a number from 1 to 6. After that, we will select the starting point in the randomization table with closed eyes, and then move on to the same row or column, and numbers that are less than or equal to 6; Are selected to reach the desired sample size of 60 (three groups of 20 people). In the present study, if we call the control group C; Later, control group patients can be divided into two groups using double blocks to form two control groups (C1 and C2). Allocation will be concealed using identical, sealed, opaque envelopes which will be ordered by number by someone outside the research team. To do this, patients' names will be coded and a list of these codes (with no other patients' demographic information) will be sent to the person outside the research team. So, the assignor person will identify each patient with a only by the allocated code.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, members of the study team and statistical analyzer will be blinded (double blind). Description: First, demographic information and study variables will be taken from all patients. Then, this information will be sent to the statistical analyzer after being coded (each code represents a patient). The statistician will randomly classify the patients into intervention and control groups, without knowing that each code belongs to which patient. After assigning each code to the intervention or control groups, the information will be transferred by the statistician to a person outside the study team. This person will place the probiotic or placebo in opaque, identical and sealed envelopes according to the patients' codes (therefore, blinding will be performed on him as well) ,and then the envelopes will be delivered to the research team members. Research team members will not have any information about the contents of each envelope (probiotic or placebo) or the information exchanged between the statistician and that person outside the research team (assigning probiotic or placebo to each code). They will deliver the envelope belonged to each patient to that patient (code) (the envelopes will be arranged in numbers, with the number of each code representing each specific patient). Patients are then asked to consume the substance in the envelope according to the instructions in their envelope. In order to measure variables, a member of the research team will measure the variables, without knowing how patients are assigned to the study groups. Then he will report the information without reporting the patient's name (using another code) to the statistician, who will analyze the results without knowing each code belongs to which intervention group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan School of Dentistry, Isfahan University of Medical Sciences, Hezar jerib street

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Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-09-01, 1400/06/10

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.160

Health conditions studied

1

Description of health condition studied
Oral health & periodontal status

ICD-10 code
K05

ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
BOP index

Timepoint
BOP measurement before intervention and 2 months after use of probiotic /placebo

Method of measurement
The number of sites where bleeding is recorded is divided by the total number of available sites in the mouth and multiplied by 100 to express the bleeding index as a percentage.

2

Description
GI index

Timepoint
GI measurement before intervention and 2 months after use of probiotic/placebo

Method of measurement
Using the gingival index classification

3

Description
PI index

Timepoint
PI measurement before intervention and 2 months after use of probiotic/placebo

Method of measurement
Using the plaque index classification

4

Description
Saliva pH number

Timepoint
PH saliva measurement before intervention and 2 months after use of probiotic/placebo

Method of measurement
PH meter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Prior to the intervention, their PI, GI, BOP and saliva PH indices will be evaluated. Then they will take a lozenge from Zist Takhmir company (Lactogum), which contains Streptococcus salivarius K12 and M12 with a concentration of 1000000000 CFU along with mint flavoring daily for 2 months. After 2 months those indices will be re-evaluated.

Category
Treatment - Drugs

2

Description
Intervention group 2: Prior to the intervention, their PI, GI, BOP and saliva PH indices will be evaluated. Then they will take a sachet from Pardis Roshd Mehrgan company (ParsiLact-/LA), which contains Lactobacillus acidophilus with a concentration of 2000000000 CFU along with Maltodextrin and Dextrose daily for 2 months. After 2 months those indices will be re-evaluated.

Category
Treatment - Drugs

3

Description
Control group 1: Prior to the intervention, their PI, GI, BOP and saliva PH indices will be evaluated. Then they will take a placebo lozenge from Zist Takhmir company, which are similar to the relevant probiotic in all respects daily for 2 months. After 2 months those indices will be re-evaluated.

Category
Placebo

4

Description

Control group 2: Prior to the intervention, their PI, GI, BOP and saliva PH indices will be evaluated. Then they will take a placebo sachet from Pardis Roshd Mehrgan company, which are similar to the relevant probiotic in all respects daily for 2 months. After 2 months those indices will be re-evaluated.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan School of Dentistry

Full name of responsible person
Saeid Sadeghian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Saeid Sadeghian

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It is possible to share study information after the patients became unidentifiable.

When the data will become available and for how long

5 months after the results are published, the information will be available.

To whom data/document is available

Researchers related to academic services and scientific journals with sufficient credibility and probiotic products companies.

Under which criteria data/document could be used

In order to use the results of the present study for similar studies or Production of probiotic products.

From where data/document is obtainable

The respondent in this regard is Amin Ansarinia and applicants can contact him at the following address: ansar.ssu@gmail.com

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

The applicant can send his request to the mentioned email address and if his eligibility for access to the information is confirmed, he will receive them within two weeks.

Comments