

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of using probiotics along with orthodontic wax on the pain and ulcers relief in patients undergoing fixed orthodontic treatment

Protocol summary

Study aim

Determination of pain intensity and number of wounds in orthodontic patients who use wax and placebo
Determination of pain intensity and number of wounds in orthodontic patients who use wax and probiotics
Comparison of pain intensity and number of wounds in orthodontic patients who use wax and placebo with patients who use wax and peiobiotic

Design

The clinical trial has a control group with a parallel group of a blinded strain, on 30 patients. A table of random numbers in sealed envelopes will be used for randomization. Patients will be divided into intervention and control groups.

Settings and conduct

36 patients over 12 years of age and candidates for fixed orthotic treatment are divided into two control groups and the target group. Random numbers table in sealed envelopes will be used for randomization. Patients will be divided into intervention and control groups. The control group receives orthodontic waxes and placebo and they are told that if the components of the orthodontic device cause an ulcer in the oral tissue, they should soften the wax in their hand and place it on the area that caused the ulcer. and take the placebo for 4 weeks by placing the lozenge in the mouth and giving it enough time to completely dissolve in the mouth. The target group also receives the same orthodontic waxes and related explanations as the control group. In addition to bromide, they will receive lactogam probiotic lozenges from the beginning of the treatment. If the patient returns earlier than 28 days due to tissue irritation, he will be excluded from the study. They are witnesses.

Participants/Inclusion and exclusion criteria

The upper age is 12 years Have good hygiene

Intervention groups

Patients consuming probiotics

Main outcome variables

Pain based on visual analogue scale number of wounds

Bleeding wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230208057356N1**

Registration date: **2023-03-29, 1402/01/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-29, 1402/01/09**

Update count: **0**

Registration date

2023-03-29, 1402/01/09

Registrant information

Name

Tannaz Abdollahzadeh baghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 8046

Email address

abdollahzadeht@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-28, 1401/12/09

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	the type of intervention is visible and recognizable. Of course, patients will be assigned to random groups.
Scientific title The effect of using probiotics along with orthodontic wax on the pain and ulcers relief in patients undergoing fixed orthodontic treatment	Placebo Used
Public title The effect of using probiotics along with orthodontic wax on the pain and ulcers relief in patients undergoing fixed orthodontic treatment	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: The upper age is 12 years A candidate to receive permanent orthodontic treatment. Have good hygiene Exclusion criteria: The woman should not be pregnant or lactating Do not have a specific (systemic) disease To consume tobacco, alcohol and any addictive substances Do not have periodontal disease Do not have a history of hypersensitivity or sensitivity to the tested substance Severely buccal or labial teeth that are prone to severe ulceration are not treated during the first sessions	Secondary Ids empty
Age From 12 years old	Ethics committees <u>1</u>
Gender Both	Ethics committee Name of ethics committee کمیته اخلاق دانشگاه علوم پزشکی تبریز
Phase 2-3	Street address Golgasht St., Tabriz University of Medical Sciences, Central Building No. 2, 3rd Floor, Research and Technology Vice-Chancellor
Groups that have been masked - Participant - Care provider	City Tabriz
Sample size Target sample size: 28	Province East Azarbaijan
Randomization (investigator's opinion) Randomized	Postal code 5165665931
Randomization description Stratified randomization based on sex. People are randomly placed in one of the two study groups with the help of a random number table and receive the intervention related to the same group. In order to hide the random allocation, the method of sealed opaque envelopes with a random sequence (envelopes opaque, sealed, numbered sequentially) will be used. In this method, each of the generated random sequences is recorded on a card and The cards are placed in the letter envelopes in order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.	Approval date 2022-10-04, 1401/07/12
Blinding (investigator's opinion) Single blinded	Ethics committee reference number IR.TBZMED.REC.1401.589
Blinding description Only the person examining the teeth will be blinded and will examine the teeth before and after the intervention without knowing which group the patient was in. The patient or his legal guardian will not be blinded because	Health conditions studied <u>1</u> Description of health condition studied بیمار دارای مال اوکلوزن ICD-10 code M26.4 ICD-10 code description Malocclusion, unspecified
	Primary outcomes <u>1</u> Description pain Timepoint 30 days after gluing the brackets Method of measurement Visual Analogue Scale
	Secondary outcomes empty

Intervention groups

1

Description

Intervention group: These patients receive orthodontic waxes and it is explained to them that if the components of the orthodontic device cause a wound in the oral tissue, they should soften the wax in their hand and place it on the part that caused the wound and until the wound heals. Renew the wax. In addition to wax, this group will receive Lactogam probiotic lozenges from the beginning of the treatment, and the method of using these lozenges will be once a day for 4 weeks after using a toothbrush and dental floss. The lozenge is placed in the mouth and given enough time to dissolve completely in the mouth. Patients will be taught to stop taking probiotics if they develop symptoms of allergy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

دانشگاه علوم پزشکی تبریز

Full name of responsible person

Pzrviz Shahabi

Street address

Golgasht St., Tabriz University of Medical Sciences,
Central Building No. 2, 3rd Floor, Research and
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research-vice@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

پرویز شهابی

Street address

Golgasht St., Tabriz University of Medical Sciences,
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Email

research-vice@tbzmed.ac.ir

Web page address

<https://researchvice.tbzmed.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mahsa Jafari Tayebpur

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Tanaz Abdullahzadeh Baghai

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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mahsa.jafariiii97@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

The results of the study will be reported in the form of articles and student theses, and raw data can be provided upon request.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions, doctors and dentists.

Under which criteria data/document could be used

The use of data for further research or therapeutic measures is permitted

From where data/document is obtainable

Katayon Katbi 00984133355965 Tabriz Dental University, Department of Oral Diseases. Katebi@tbzmed.ac.ir

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

The applicant sends request via email and the information and data are sent to email.

Comments