

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Clinical trial The Effect of Probiotic Supplementation in the form of Mouthwash with Scaling and Root planing on the Periodontal Indices in Patients with Generalized Chronic Periodontitis

#### Protocol summary

##### Study aim

This study aims to determine the Effect of Probiotic Supplementation in the form of Mouthwash with Scaling and Root planing on the Periodontal Indices in Patients with Generalized Chronic Periodontitis

##### Design

36 patients with Chronic Generalized Periodontitis will be chosen and will be divided into two equal groups through simple randomization.

##### Settings and conduct

Probiotic and placebo supplements in the same packages (shape, size, and color that are almost the same). The supplements will be purchased from Milad Faramed company and will be available to patients.

##### Participants/Inclusion and exclusion criteria

Healthy patients aged 25-59 years old, with a average age of 45.3 years who are diagnosed with chronic periodontitis with at least 4 teeth indicating probing depth (PD)  $\geq$  5 mm, clinical attachment level (CAL)  $\geq$  4 mm will be chosen. include criteria: Patients suffering Chronic Generalized Periodontitis with a degree of Clinical adhesion of CAL  $\geq$  4 who are systemically healthy. Exclude criteria: Patients with any systemic disease, that could affect periodontum disease Sensitivity to probiotic supplements Antibiotic therapies in the last 3 months Pregnant and lactating women Allergic patients to lactate products Patients with inappropriate collaboration (High level of plaque index in the periodic examinations).

##### Intervention groups

The intervention group after SRP will use probiotic for 20 days by daily solution of two probiotic capsules in 250 cc in water and then will gargle in the mouth for 30 to 60 seconds to increase its local effect on the gum tissue.

##### Main outcome variables

Measuring the variables (Bleeding on probing, Probing depth, Clinical attachment loss, Plaque index) before scaling, and in the period of one month and three

months after scaling.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180630040290N2**

Registration date: **2019-03-27, 1398/01/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-27, 1398/01/07**

Update count: **0**

##### Registration date

2019-03-27, 1398/01/07

##### Registrant information

##### Name

Amir Reza Babaloo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3428 3025

##### Email address

babalooa@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-01, 1397/12/10

##### Expected recruitment end date

2019-04-30, 1398/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Clinical trial The Effect of Probiotic Supplementation in the form of Mouthwash with Scaling and Root planing on the Periodontal Indeces in Patients with Generalized Chronic Periodontitis

## Public title

The Effect of Probiotic Supplementation in the form of Mouthwash with Scaling and Root planing on the Periodontal Indeces in Patients with Generalized Chronic Periodontitis

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients suffering chronic generalized periodontitis with clinical attachment loss (CAL)≥4 millimeters who are systemically healthy.

### Exclusion criteria:

Patients with any systemic disease, that could affect periodontium disease Sensitivity to probiotic supplements Antibiotic therapies in the last 3 months Pregnant and lactating women Allergic patients to lactate products Patients with inappropriate collaboration (High level of plaque index in the periodic examinations)

## Age

From **29 years** old to **59 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization. In this study, patients are assigned to one of two study groups using the random number table.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Probiotic and placebo supplements are in the same packages (shape, size, and color that are almost the same). The supplements will be purchased from Milad Pharmed company and will be available to patients.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Central office of Tabriz University of Medical Sciences, Goltasht Ave, Azadi Blv

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165687386

#### Approval date

2019-02-05, 1397/11/16

#### Ethics committee reference number

IR.TBZMED.REC.1397.912

## Health conditions studied

### 1

#### Description of health condition studied

The effect of probiotic supplementation in the form of mouthwash with scaling and root planing on the periodontal indeces in patients with generalized chronic periodontitis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Clinical attachment level (CAL)

#### Timepoint

Before the intervention , one months after initiating the intervention and three months after initiating the intervention.

#### Method of measurement

measurement of the distance between the stent margin to the sulcus base by means of a periodontal probe.

### 2

#### Description

Plaque index (PI)

#### Timepoint

Before the intervention , one months after initiating the intervention and three months after initiating the intervention.

#### Method of measurement

By disclosing agent with visual scale.

### 3

#### Description

Bleeding on probing (BOP)

#### **Timepoint**

Before the intervention , one months after initiating the intervention and three months after initiating the intervention.

#### **Method of measurement**

Bleeding in 15 seconds after gentle probing by periodontal probe.

### **4**

#### **Description**

Probing depth (PD)

#### **Timepoint**

Before the intervention , one months after initiating the intervention and three months after initiating the intervention.

#### **Method of measurement**

The distance between the mucosal margin and the sulcus base by periodontal probe in millimeters.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The intervention group after SRP will use probiotic for 20 days by daily solution of two probiotic capsules in 250 cc water and then will gargle in the mouth for 30 to 60 seconds to increase its local effect on the gum tissue.

#### **Category**

Treatment - Other

### **2**

#### **Description**

The control group after SRP will use placebo (drinking water that has been established in terms of chemical compounds).

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Dental Clinic of Faculty of Dentistry of Tabriz

##### **Full name of responsible person**

Amirreza Babaloo

##### **Street address**

Dentistry Faculty of Tabriz, Golgasht Ave, Azadi Blvd.

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614711

##### **Phone**

+98 41 3335 5921

##### **Email**

amirrezababaloo@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Abolghasem Jouyban

##### **Street address**

Central office No. 2, Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

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East Azarbaijan

##### **Postal code**

5166614711

##### **Phone**

+98 41 3335 7310

##### **Email**

ajouyban@hotmail.com

##### **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**

Other

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Amirreza Babaloo

##### **Position**

Assistant Professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Dentistry

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Dentistry faculty, Tabriz University of Medical Sciences, Golgasht Ave

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Tabriz

**Province**

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**Postal code**

5166614711

**Phone**

+98 41 3335 5921

**Email**

Amirrezababaloo@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Amirreza Babloo

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Behnam Mohammadi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Email**

behnam.mhmdi739298@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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available