Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

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 Indeces in Patients with Generalized Chronic Periodontitis

Design

36 patients with Chronic Generalized Periodontitis will be choosen 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) ≥ 5 mm, clinical attachment level (CAL) ≥4 mm will be choosen. include criteria: Patients suffering Chronic Generalized Periodontitis with a degree of Clinical adhesion of CAL≥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)

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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, Golgasht 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 stablished 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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

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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Person responsible for scientific inquiries

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Other areas of specialty/work
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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