

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of topical administration (mouthwash) of capsules containing probiotics in the treatment of patients with pre-implantitis (clinical trial)

Protocol summary

Study aim

The aim is to compare the improvement of patients with pre-implantitis after scaling and taking probiotic tablets as a mouthwash with patients with pre-implantitis after scaling and taking placebo as mouthwash.

Design

randomized trial with blinded postoperative care and outcome assessment and patient design of 70 patient

Settings and conduct

In the specialized dental clinic, after measuring the depth of the envelope and bleeding during the probe around the implant, if it has pre-implantitis conditions, scaling is performed, it is divided into two groups, one capsule containing probiotics and the other group is given a placebo. 0-14-30days after the first examination, they are reviewed. In this study, the patient measuring and analyzer are blinded Blocked method

Participants/Inclusion and exclusion criteria

age 30-60 peri-implantitis index do not allergy to probiotic

Intervention groups

The intervention group received 14 capsules containing probiotics, which dissolved one capsule in two tablespoons of lukewarm water every night and used as a mouthwash for 14 nights. The control group receiving placebo 14 capsules is a form of placebo that dissolves one capsule in two tablespoons of lukewarm water every night and uses it as a mouthwash for 14 nights.

Main outcome variables

depth of packet around implant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190101042195N1**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Farzane Eivani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 7458

Email address

eivani.farzane@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-10, 1399/06/20

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical administration (mouthwash) of capsules containing probiotics in the treatment of patients with pre-implantitis (clinical trial)

Public title

Effect of Probiotic in treatment of peri-implantitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30-60 years Preimplantitis index Do not allergy to probiotics

Exclusion criteria:

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Block This method is used to prevent eye imbalance in the number of manufacturing companies that are assigned to each group. Block liquidation ensures that it is not approved at any time during the refund period, but can not be validated in other power groups, and if some of the companies in each group are equal, this method requires that each block be specified. (Types of quadruple blocks). Then write the list of blocks and assign the numbers (AABB (1) - ABAB (2) -ABBA (3) - BBAA (4) - BABA (5) - BAAB (6) after selecting random numbers between one and 6 (Eg 1 4 5, etc.) and finally it is determined that it cures the specified list before (ad AABB-BBAA-BABA-).} The concealment is sealed envelope

Blinding (investigator's opinion)

Triple blinded

Blinding description

Origin researcher and analyzer and patient are unaware of control and intervention groups

Placebo

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

Mashhad Dentistry School,Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2020-06-27, 1399/04/07

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.014

Health conditions studied

1

Description of health condition studied

Peri-implantitis

ICD-10 code

K05.6

ICD-10 code description

Diseases of oral cavity, salivary glands and jaws, Periodontal disease, , unspecified

Primary outcomes

1

Description

Measure the depth of the pocket around the implant

Timepoint

Measure the depth of the pocket at the beginning of the study and 14,30 days after the start of probiotic use

Method of measurement

probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients are scaled and given capsules of a pre-coded form (for two weeks and once a day). The intervention group is given 14 capsules containing probiotics, brand Gerilact. every night Dissolve one capsule in two tablespoons of warm water and hold it in the mouth as a mouthwash for one to two minutes and then take it out. Patients are re-evaluated after the first examination, 14 days after the first examination and 30 days after the first examination.

Category

Treatment - Drugs

2

Description

Control group: Patients are scaled and 14 capsules of

one form and pre-coded placebo are given for two weeks and once a day. Every night, the contents of one capsule are dissolved in two tablespoons of lukewarm water and mouthwash for one to two minutes and then taken out. 14 days and 30 days after the first examination ,Will be re-evaluated

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Naser Sargolzaei

Street address

Mashhad Dental School, Vakilabad Blvd,

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7000

Email

j.m.dental.s@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Bagherih

Street address

Mashhad Dental School, Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7000

Email

j.m.dentistry@yahoo.com

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

Naser Sargolzaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Mashhad Dental School , Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7000

Email

sargolzaein@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Naser Sargolzaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Mashhad Dental School , Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7000

Email

sargolzaein@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Naser Sargolzaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Mashhad Dental School , Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7000

Email

sargolzaein@mums.ac.ir

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