

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Analysis of the clinical and bacteriological effects scaling and root planing with assumption of synbiotic product or placebo as the complementary treatment in patients with chronic periodontitis

Protocol summary

Study aim

The major purpose of periodontal therapy is to eliminate all bacterial deposits on the tooth surfaces and progression of clinical parameters. Probiotic is a promising treatment method that can be useful as an adjunct treatment to conventional therapy of periodontitis. The aim of this clinical trial is to compare the clinical and bacteriological effects of scaling & root planing with taking placebo or synbiotic product as an adjunct treatment.

Design

Interventional, randomized, single blind, Unicenter, with placebo, parallel clinical trial

Settings and conduct

Patient were randomly divided into control and intervention groups. Microbiological samples were collected from all patients at baseline and 30 days after treatment and also clinical parameters including pocket depth, clinical attachment loss, bleeding on probing initially and 30 days after treatment, were measured.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patient with physical and mental health who were not treated for periodontitis during the last two years, did not use probiotic food products during the past year, who had at least 10 to 12 areas with the pocket depth of 3mm that bleeding on probing. Exclusion Criteria: subjects with history of uncontrolled diabetes, AIDS, rheumatic fever, severe hepatic and renal problems, deficiency in immunological and neurological systems, patients consuming any type of medicine that affect periodontal tissue, pregnant and lactating women, smokers and alcoholic patients, subjects a pocket depth of more than 6 mm.

Intervention groups

Patient with mild to moderate chronic periodontitis who had at least 10 to 12 areas with the pocket depth of 3mm that bleeding on probing.

Main outcome variables

Primary Result: count of Porphyromonas gingivalis in subgingival plaque. Secondary consequence: evaluation of mentioned clinical parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130216012487N7**

Registration date: **2020-11-22, 1399/09/02**

Registration timing: **retrospective**

Last update: **2020-11-22, 1399/09/02**

Update count: **0**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

Shirin Amini

Name of organization / entity

Khorasgan Branch, Islamic Azad University, Isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-06, 1396/08/15

Expected recruitment end date

2018-07-19, 1397/04/28

Actual recruitment start date

2017-11-06, 1396/08/15

Actual recruitment end date

2018-09-04, 1397/06/13

Trial completion date

2018-12-28, 1397/10/07

Scientific title

Analysis of the clinical and bacteriological effects scaling and root planing with assumption of synbiotic product or placebo as the complementary treatment in patients with chronic periodontitis

Public title

Clinical and bacteriological Effects of Synbiotic as an Adjunct in Phase I Periodontal Therapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with complete physical and mental health Who were not treated for periodontitis during the last two years Who did not use probiotic food products during the past year Who have at least 10 to 12 areas with the pocket depth of 3mm to 6 mm with bleeding on probing.

Exclusion criteria:

subjects with history of uncontrolled diabetes, AIDS, rheumatic fever, severe hepatic and renal problems, deficiency in immunological and neurological systems patients consuming any type of medicine that affect periodontal tissue (Phenytoin, Cyclosporine and Nifedipine) pregnant and lactating women smokers and alcoholic subjects subjects with a pocket depth of more than 6 mm

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **28**Actual sample size reached: **28****Randomization (investigator's opinion)**

Randomized

Randomization description

patients were randomly selected via throwing the coin to treat by one of the treatment

Blinding (investigator's opinion)

Double blinded

Blinding description

All the variables were measured and microbial sampling was carried out by another examiner who was blind to the selected treatment modalities for each tooth.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan Branch, Islamic Azad University

Street address

Isfahan Branch, Islamic Azad University, University Boulevard, Arghavaniyeh street, Eastern Jey Street, Isfahan

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Isfahan

Province

Isfahan

Postal code

8155139998

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

2659-2-14-04

Health conditions studied**1****Description of health condition studied**

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes**1****Description**

count of Porphyromonas gingivalis in subgingival plaque

Timepoint

At baseline and 30 days after intervention

Method of measurement

Dilution and culture of bacteria samples in riched solid blood agar and black pigmentation of Porphyromonas gingivalis visual colony counting and microscopic experiments for detection of the gram negative bacillus of Porphyromonas gingivalis and biochemical tests.

Secondary outcomes**1****Description**

Measuring pocket depth

Timepoint

At baseline and 30 days after intervention

Method of measurement

Measuring of pocket depth in mm by a University of Michigan probe with Williams markings

2

Description

Measuring clinical attachment loss

Timepoint

At baseline and 30 days after intervention

Method of measurement

Measuring of clinical attachment loss in mm by University of Michigan with Williams markings probe

3

Description

Evaluation of bleeding on probing

Timepoint

At baseline and 30 days after intervention

Method of measurement

Probing by University of Michigan with Williams markings probe and then clinical absevation

Intervention groups

1

Description

Intervention group: Dissolve 1 sachet synbiotic Product in 30ml water and use it as mouthwash twice a day after tooth brushing

Category

Treatment - Drugs

2

Description

Control group: Dissolve 1 sachet of placebo in 30ml water and use it as mouthwash twice a day after tooth brushing

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology, Dental School, Isfahan Branch, Islamic Azad University

Full name of responsible person

Amini, Shirin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Research Vice- Chancellor of Islamic Azad University Isfahan Branch

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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

6

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

Dental School, Isfahan Branch, Islamic Azad University

Full name of responsible person

Shirin amini

Position

Assistant Professor/ DDS, MSc

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Other areas of specialty/work

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

Dental School, Isfahan Branch, Islamic Azad
University

Full name of responsible person

Maghamipour, Nasim

Position

Periodontics resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

No - There is not 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

The documentation for this study is available to other
researchers. Available documents will include data
related to all studied variables (except patients' personal
information) and in the form of SPSS file.

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

The information of this research can be shared with all
academic researchers.

Under which criteria data/document could be used

For research and clinical use

From where data/document is obtainable

Ways of communication with the responsible researcher:
Email: sh.amini@khuisf.ac.ir

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

After coordination with the responsible researcher, the
requested data will be sent within one month.

Comments