Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Analysis of the clinical and bacteriological effects scailing 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)
Phone
+98 31 1535 4053
Email address
sh.amini@khuisf.ac.ir

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 scailing 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
City
Isfahan
Province
Isfehan
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 bactery 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 Wiliams 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 Wiliams 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 Wiliams 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
Street address
خیابان جی-خیابان ارغوانیه-دانشکده دندانپزشکی دانشگاه آزاداسلامی واحد اصفهان
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 1535 4053
Email
Sh.amini@khuisf.ac.ir

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
Street address
Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 4545 6779
Email
esfahanian@khuisf.ac.ir
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

Street address
Dental School, Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 1535 4053
Email
Sh.amini@khuisf.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Dental School, Isfahan Branch, Islamic Azad University
Full name of responsible person
Amini, Shirin
Position
Assistant Professor/ DDS, MSc
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Dental School, Isfahan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan,
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 1535 4053
Email
Sh.amini@khuisf.ac.ir

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
Street address
Dental School, Isfahan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 913 327 3293
Email
maghamipour2013@gmail.com

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