

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Impact of probiotic supplementation in Adjunct with Non-surgical periodontal Therapy on Periodontal and antioxidant status in periodontal patients with type 2 diabetes mellitus

Protocol summary

Study aim

Determination the Effect of Probiotic Supplementation in adjunct with Non-surgical Periodontal Therapy on Periodontal and Antioxidant Status in Type 2 Diabetic Patients with Periodontal Disease

Design

In this randomized clinical trial, 50 diabetic patients with chronic periodontitis are selected and allocated to two groups involve intervention (n=25) and control (n=25) groups. The intervention group receives probiotic supplement (500 mg as capsulated) and the control group receives placebo capsules containing wheat flour (500 mg) for 8 weeks. Non-surgical periodontal therapy is performed for all patients during this study. Some demographic data including age, sex; anthropometric indices such as weight, height, BMI, waist and hip circumference; biochemical indices including Total antioxidant capacity, blood levels of malondialdehyde, superoxide dismutase and glutathione peroxidase enzymes activity; periodontal indices (bleeding index, pocket depth, plaque index and clinical attachment loss) and a 3 days dietary record are evaluated pre and post intervention.

Settings and conduct

fifty patients with T2DM were recruited for this study from the endocrinology clinic of golestan Hospital in Ahwaz, Iran. Then, patient with inclusion criteria and some symptoms of periodontal disease were referred to Dental Clinic for further diagnosis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Males and females aged (30 - 60 y); type 2 diabetic patients (at least 5 years of diagnosis) with chronic periodontal disease; $30 < \text{BMI} \leq 18.5 \text{ kg/m}^2$
Exclusion criteria: Diabetic complications such as renal failure; using insulin therapy; pregnancy; breast feeding; traveling greater than 1 weeks; smoking; using any dietary supplements including probiotic and antioxidant

supplements; using immunosuppressive medications; history of periodontal therapy; following specific diet; changing usual diet and planning to weight loss

Intervention groups

The intervention group receive probiotic supplement (500 mg as capsulated) for 8 weeks. the control group receive placebo capsules containing wheat flour (500 mg) for 8 weeks.

Main outcome variables

Total antioxidant capacity; blood levels of malondialdehyde; superoxide dismutase activity; glutathione peroxidase activity; bleeding index; pocket depth; plaque index; clinical attachment loss

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20161104030694N2**

Registration date: **2018-01-15, 1396/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-15, 1396/10/25**

Update count: **0**

Registration date

2018-01-15, 1396/10/25

Registrant information

Name

Mohsen Yarahmadi

Name of organization / entity

Jondishapoor ahvaz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 1257

Email address

jarahmadi.m@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-10-23, 1396/08/01
Expected recruitment end date
2018-03-21, 1397/01/01
Actual recruitment start date
2017-10-23, 1396/08/01
Actual recruitment end date
2018-03-21, 1397/01/01
Trial completion date
empty

Scientific title
Impact of probiotic supplementation in Adjunct with Non-surgical periodontal Therapy on Periodontal and antioxidant status in periodontal patients with type 2 diabetes mellitus

Public title
Impact of probiotic supplementation in treatment of periodontal patients with type 2 diabetes mellitus

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Males and females aged (30 – 60 y) type 2 diabetic patients (at least 5 years of diagnosis) with chronic periodontal disease $18.5 \leq \text{BMI} < 30$

Exclusion criteria:
Diabetic complications such as renal failure using insulin therapy pregnancy breast feeding traveling greater than 1 weeks smoking using any dietary supplements including probiotic and antioxidant supplements using immunosuppressive medications history of periodontal therapy following specific diet changing usual diet and planning to weight loss

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **47**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization by using closed bags

Blinding (investigator's opinion)
Double blinded

Blinding description

In this study, the supplement and placebo were produced by zist takhmir company in the same packages. All packets have code that participants, investigators, and data analyzer were unaware of which package is probiotic supplement and which one is a placebo.

Placebo
Used
Assignment
Parallel
Other design features
Randomization by using closed bags

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Joudishapour University of Medical Science

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan street

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2017-07-18, 1396/04/27

Ethics committee reference number

ir.ajums.NRC.1396.9612

Health conditions studied

1

Description of health condition studied

Impact of probiotic supplementation on periodontal indices and anti-oxidant status in periodontal patients with type 2 diabetes mellitus

ICD-10 code

E11, K04.5

ICD-10 code description

Non-insulin-dependent diabetes mellitus, Chronic periodontitis

Primary outcomes

1

Description

Pocket dept

Timepoint

Immediately Before and after the intervention

Method of measurement

The probing depth is measured by the probe

Secondary outcomes

1

Description

Plaque index

Timepoint

Immediately Before and after the intervention

Method of measurement

Plaque is on the tooth surface

Intervention groups

1

Description

Intervention group: The intervention group receive probiotic supplement (500 mg as capsulated) for 8 weeks.

Category

Other

2

Description

Control group: the control group received one pill/day placebo in the same packing like probiotic supplements that contained the same substance without bacteria.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Golestan Hospital

Full name of responsible person

mohsen yarahmadi

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street, Ahvaz, Khosetan,Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 74 3333 1257

Fax

+98 74 3333 1257

Email

yarahmadi14671@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. behzad sharif makhmalzadeh

Street address

Vice Chancellor for research of Ahvaz Jundishapur
University of Medical Sciences, Golestan street,
Ahvaz, Khosetan,Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 74 3333 1257

Fax

+98 74 3333 1257

Email

yarahmadi14671@gmail.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Ahmad Zarejavid

Position

Professor of Ahvaz Jundishapur University of Medical
Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street, Ahvaz, Khosetan,Iran

City

Ahvaz

Province

Khouzestan
Postal code
61357-15794
Phone
+98 74 3333 1257
Email
yarahmadi14671@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ahmad Zarejavid
Position
Professor of Ahvaz Jundishapur University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ahvaz Jundishapur University of Medical Sciences,
Golestan street, Ahvaz, Khosetan,Iran
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 74 3333 1257
Email
yarahmadi14671@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ahmad Zarejavid
Position
Professor of Ahvaz Jundishapur University of Medical Sciences
Latest degree
Ph.D.

Other areas of specialty/work

Nutrition
Street address
Ahvaz Jundishapur University of Medical Sciences,
Golestan street, Ahvaz, Khosetan,Iran
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 74 3333 1257
Email
yarahmadi14671@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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Information about the original outcome will be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions and businesses

Under which criteria data/document could be used

Any use of data is permitted.

From where data/document is obtainable

Mobile number: 00989170438074

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

Immediately after the call, the data will be provided to the caller.

Comments