Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 < BMI ≥ 18.5 kg/m2 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)

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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 ≤ 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
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Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr. behzad sharif makhmalzadeh
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Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan,Iran
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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
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Person responsible for updating data

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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
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