

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Impact of probiotic supplementation on periodontal indices, lipid profile, inflammatory markers and Glycemic Control in periodontal patients with type 2 diabetes mellitus

Protocol summary

Summary

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 fasting blood glucose, HbA1c, lipid profile, inflammatory markers such as IL-6, hs-CRP and TNF-a; periodontal indices (bleeding index, pocket depth, plaque index and clinical attachment loss) and a 3 days dietary record are evaluated pre and post intervention.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016110430694N1**
Registration date: **2017-01-28, 1395/11/09**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-28, 1395/11/09

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

yarahmadi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Joudishapour University of Medical Science

Expected recruitment start date

2016-11-15, 1395/08/25

Expected recruitment end date

2017-01-14, 1395/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of probiotic supplementation on periodontal indices, lipid profile, inflammatory markers and Glycemic Control 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; BMI $\geq 18.5 < 30$ 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

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Postal code

61357-15794

Approval date

2016-11-01, 1395/08/11

Ethics committee reference number

ir.ajums.rec.1395.452

Health conditions studied

1

Description of health condition studied

Impact of probiotic supplementation on periodontal indices, lipid profile, inflammatory markers and Glycemic Control 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

Fasting blood sugar

Timepoint

Immediately Before and after the intervention

Method of measurement

Using enzymatic kits

2

Description

IL-6

Timepoint

Immediately Before and after the intervention

Method of measurement

Elisa

3

Description

Hb-A1c

Timepoint

Immediately Before and after the intervention

Method of measurement

Elisa

4

Description

hs-CRP

Timepoint

Immediately Before and after the intervention

Method of measurement

Elisa

5

Description

TNF-a

Timepoint

Immediately Before and after the intervention

Method of measurement

Elisa

6

Description

total cholesterol

Timepoint

Immediately Before and after the intervention

Method of measurement

Using enzymatic kits

7

Description

HDL-C

Timepoint

Immediately Before and after the intervention

Method of measurement

Using enzymatic kits

8

Description

LDL-C

Timepoint

Immediately Before and after the intervention

Method of measurement

Using enzymatic kits

9

Description

TG

Timepoint

Immediately Before and after the intervention

Method of measurement

Using enzymatic kits

10

Description

Bleeding during probe

Timepoint

Immediately Before and after the intervention

Method of measurement

Evaluation of bleeding

11

Description

Plaque index

Timepoint

Immediately Before and after the intervention

Method of measurement

Plaque is on the tooth surface

12

Description

Pocket dept

Timepoint

Immediately Before and after the intervention

Method of measurement

The probing depth is measured by the probe.

13

Description

Clinical attachment level

Timepoint

Immediately Before and after the intervention

Method of measurement

Depth study of cement and enamel plaque periodontal

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Other

2

Description

control: the control group receive placebo capsules containing wheat flour (500 mg) for 8 weeks.

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ahvaz Jundishapur
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

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Ahvaz Jundishapur

University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

mohsen yarahmadi

Position

Master student of nutrition

Other areas of specialty/work**Street address**

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mohsen yarahmadi

Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Ahmad Zarejavid

Position

Professor of Ahvaz Jundishapur University of Medical
Sciences

Other areas of specialty/work**Street address**