

# 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/m<sup>2</sup>  
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  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Dr. Ahmad Zarejavid  
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## Person responsible for updating data

### Contact

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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*