

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effects of probiotics on lipid profile, glycemic index, oxidative stress and inflammatory markers in patients with diabetes type 2; a clinical trial study

#### Protocol summary

##### Summary

Objective: the effect of probiotics on the biochemical parameters as markers of cardiovascular disease in patients with type 2 diabetes. Inclusion and Exclusion Criteria: Patients with diabetes type 2 are enrolled with FBS $\geq$ 126 mgr/dl and less than 15 years of medical history and the age range was 25 to 65 years. Elective subjects should not use alternative treatments like Hormone therapy or supplemental vitamin. Also those patients with chronic kidney disease, liver, lung and chronic or acute inflammatory disease, heart valve disease, short bowel syndrome and allergies and also, people with low immune system ability (autoimmune) and pregnant or lactating women, were removed. Population and sample size: Forty patients with type 2 diabetes among people eligible to participate and referred to PERSIAN GULF HOSPITAL, was selected. Intervention: These patients were divided to either an intervention (receiving probiotic capsule) or placebo (receiving placebo) groups. After an overnight fasting, subjects referred for blood drawn. After this stage, blood samples tested. After six weeks, fasting blood samples were tested again. The beginning and end of the study: 6 weeks (SEPTEMBER 6, 2010 - NOVEMBER 6, 2010) Outcomes: Baseline serum LDL-C, HDL-C, TG and total cholesterol, glucose, insulin, malondialdehyde, hs-CRP and IL-6.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016071127879N2**  
Registration date: **2016-09-22, 1395/07/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-22, 1395/07/01

##### Registrant information

###### Name

Abbas Yousefinejad

###### Name of organization / entity

Bushehr University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 77 3345 0178

###### Email address

a.yousefinezhad@bpums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Bushehr University of Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2016-10-21, 1395/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of probiotics on lipid profile, glycemic index, oxidative stress and inflammatory markers in patients with diabetes type 2; a clinical trial study

##### Public title

Effects of probiotics on lipid profile, glycemic index, oxidative stress and inflammatory markers in patients

with diabetes type 2

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: Patients with diabetes type 2 are enrolled with FBS $\geq$ 126 mgr/dl; less than 15 years of medical history; the age range is 25 to 65 years; the elective subjects, next drugs prescribed by physicians, should be controlled the status of glucose and lipid levels and during the study could use these drugs without changing in the prior dosage. Exclusion Criteria: Patients with diabetes type 2 that used alternative treatments like hormone therapy or supplemental vitamins; also those used tobacco and alcohol; patients with chronic kidney disease; liver, lung, chronic or acute inflammatory disease (especially acute pancreatic inflammation and Endocarditis); heart valve disease; short bowel syndrome; allergies; people with low immune system ability (autoimmune); pregnant or lactating women.

## Age

From **25 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Bushehr University of Medical Sciences

##### Street address

Bushehr University of Medical Sciences

##### City

Bushehr

##### Postal code

#### Approval date

2016-07-18, 1395/04/28

#### Ethics committee reference number

IR.BPUMS.REC.1395.64

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 Diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

Lipid Profile (Tg, Total Chol, LDL-C, HDL-C)

#### Timepoint

Before and After Intervention

#### Method of measurement

Autoanalyzer

### 2

#### Description

Serum Glucose

#### Timepoint

Before and after Intervention

#### Method of measurement

Autoanalyzer

### 3

#### Description

Serum Insulin Levels

#### Timepoint

Before and After Intervention

#### Method of measurement

ELISA

### 4

#### Description

hs-CRP

#### Timepoint

Before and after intervention

#### Method of measurement

ELISA

### 5

#### Description

IL-6

#### Timepoint

Before and After Intervention

#### Method of measurement

Autoanalyzer

### 6

#### Description

Malodialdehyde (MDA)

#### Timepoint

Before and after Intervention  
**Method of measurement**  
Specterophotometry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention: patients in the treatment group received 1500 mg probiotic capsules twice daily (after lunch and dinner meals) for 6 weeks. The lactobacillus Probiotics contain: L. acidophilus 3.6 billion (×10<sup>9</sup> CFU) L. bulgaricus 600 million (×10<sup>6</sup> CFU) L. bifidum 600 million (×10<sup>6</sup> CFU) L. casei 1.2 billion (×10<sup>9</sup> CFU)

#### Category

Treatment - Drugs

### 2

#### Description

Control: Placebo Group receiving 1500 mg Magnesium Stearate capsules twice daily, for six weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
PERSIAN GULF HOSPITAL of BUSHEHR  
**Full name of responsible person**  
Hanieh Nozari  
**Street address**  
**City**  
BUSHEHR

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Bushehr University of Medical Sciences  
**Full name of responsible person**  
Samira Zare  
**Street address**  
Research Deputy of Bushehr University of Medical Sciences, Bahmani St, Bushehr, Iran  
**City**  
Bushehr  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

#### Title of funding source

Bushehr 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

Bushehr University of Medical Sciences

##### Full name of responsible person

Abbas Yousefinejad

##### Position

PhD/Assistant Professor

##### Other areas of specialty/work

##### Street address

Bushehr University of Medical Sciences, Bahmani St,  
Bushehr, Iran

##### City

Bushehr

##### Postal code

##### Phone

+98 77 3345 0134

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yousefinejad.abs@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Bushehr University of Medical sciences

##### Full name of responsible person

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PhD

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Abbas Yousefinejad

**Position**

PhD

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

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**City**

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**Postal code****Phone**

+98 77 3345 0134

**Fax****Email****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*