

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Effect of probiotic supplementation on glycemic, inflammatory indices, blood lipids and body composition in prediabetic patients

#### Protocol summary

##### Summary

60 prediabetic patients admitted to the Endocrine and Metabolism Research Center-Isfahan University of Medical Sciences will be included in the study, after completing consent forms, the subjects will be randomly assigned to either intervention or placebo groups. Demographic information and laboratory results will be designed for each subject, before and after intervention. Dietary measurements will be performed by using food frequency questionnaire and 24 hour dietary recall. Height will be measured by stadiometer with 0.5 cm precision in normal standing position. Body composition (including weight, lean body mass, soft lean mass, total body water, body fat, protein, mineral, body mass index, abdominal circumference, waist to hip ratio, and basal metabolic rate) will be assessed by Body Composition Analyzer, while the subject is wearing light clothes with bare feet and hands. Subjects will receive either probiotics or placebo once a day for 8 weeks. We will call or text subjects once a week to remind them to take the capsules regularly. An expert dietitian will keep in touch with subjects to solve any problems if there is some.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013022411763N5**  
Registration date: **2013-08-06, 1392/05/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-06, 1392/05/15

##### Registrant information

**Name**

Gholamreza Askari

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2110

##### Email address

askari@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Isfahan University of Medical Sciences

##### Expected recruitment start date

2012-12-01, 1391/09/11

##### Expected recruitment end date

2013-08-21, 1392/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of probiotic supplementation on glycemic, inflammatory indices, blood lipids and body composition in prediabetic patients

##### Public title

probiotics and prediabetes

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

all prediabetic patients at the age range of 25 to 65 years old with fasting plasma glucose between 100 and 125 mg/dl and glucose tolerance test between 140 to 200 mg/dl are included in the study, study subjects must have an steady state of glycemic and lipid control and

drug usage. patients with chronic hepatic, renal, heart and acute inflammatory diseases are not included in the study. patients who have allergic responses to probiotics or those who want to give up following the study or those who have not taken their probiotics will be excluded from the study.

#### **Age**

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

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Isfahan Regional Bioethics Committee

##### **Street address**

Isfahan University of Medical Sciences, Hezarjarib St.,  
Isfahan

##### **City**

Isfahan

##### **Postal code**

81745319

#### **Approval date**

2010-09-23, 1389/07/01

#### **Ethics committee reference number**

329157

## **Health conditions studied**

### 1

#### **Description of health condition studied**

prediabetes

#### **ICD-10 code**

E-11

#### **ICD-10 code description**

Non-insulin-dependent diabetes mellitus

## **Primary outcomes**

### 1

#### **Description**

fasting blood glucose

#### **Timepoint**

the first day of the study and the last day of 8th week

#### **Method of measurement**

Colorimetry

### 2

#### **Description**

glycated hemoglobin(HbA1C)

#### **Timepoint**

the first day of the study and the last day of 8th week

#### **Method of measurement**

Ion exchange chromatography

### 3

#### **Description**

Total serum cholestrol

#### **Timepoint**

the first day of the study and the last day of 8th week

#### **Method of measurement**

Enzymatic assay with autoanalyser

### 4

#### **Description**

Serum triglycerides

#### **Timepoint**

the first day of the study and the last day of 8th week

#### **Method of measurement**

Enzymatic assay with autoanalyser

### 5

#### **Description**

Serum low density lipoprotein

#### **Timepoint**

the first day of the study and the last day of 8th week

#### **Method of measurement**

Enzymatic assay with autoanalyser

### 6

#### **Description**

Serum High density lipoprotein

#### **Timepoint**

The first day of the study and the last day of 8th week

#### **Method of measurement**

Enzymatic assay with autoanalyser

### 7

#### **Description**

Erythrocyte sedimentation rate

#### **Timepoint**

The first day of the study and the last day of 8th week

#### **Method of measurement**

Instrumental analysis method

## 8

### **Description**

High sensitive C- Reactive Protein

### **Timepoint**

The first day of the study and the last day of 8th week

### **Method of measurement**

Turbidimetric Method

## **Secondary outcomes**

## 1

### **Description**

Height

### **Timepoint**

The first day of the study and the last day of 8th week

### **Method of measurement**

Stadiometer

## 2

### **Description**

Body composition

### **Timepoint**

the first day of the study and the last day of 8th week

### **Method of measurement**

BIA method

## 3

### **Description**

Blood pressure

### **Timepoint**

The first day of the study and the last day of 8th week

### **Method of measurement**

Pressure indicator

## **Intervention groups**

## 1

### **Description**

Probiotic Familact, 500 miligrams capsules, once a day (with lunch), for 60 days.

### **Category**

Treatment - Drugs

## 2

### **Description**

Placebo

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

### **Name of recruitment center**

The endocrine and metabolism research center, Isfahan University of Medical Sciences.

### **Full name of responsible person**

Dr.Gholamreza Askari

### **Street address**

Department of Community Nutrition, School of Nutrition and Food sciences, Isfahan University of Medical Sciences

### **City**

Isfahan

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

#### **Full name of responsible person**

Dr.Peyman.Adibi

#### **Street address**

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

#### **City**

Isfahan

#### **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, Isfahan University of Medical Sciences

#### **Proportion provided by this source**

#### **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*

## 2

### **Sponsor**

#### **Name of organization / entity**

Research Deputy of Isfahan University of Medical Sciences

#### **Full name of responsible person**

Doctor Peyman Adibi

#### **Street address**

Isfahan University of Medical Sciences, Hezarjarib St., Isfahan

#### **City**

Isfahan

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Research Deputy of Isfahan University of Medical Sciences

**Proportion provided by this source****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**

Isfahan University Of Medical Sciences

**Full name of responsible person**

Sepideh.Mahboobi

**Position**

MSc student of Nutrition

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

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sepidmahboobi@gmail.com

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Isfahan University Of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Askari

**Position**

Ph.D of nutrition, Assistant Professor

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Sepideh.Mahboobi

**Position**

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**City**

Isfahan

**Postal code****Phone**

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**Fax****Email**

sepidmahboobi@gmail.com

**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