

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**

Department of Community Nutrition School of Nutrition and Food Sciences Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 1792 2110

Fax**Email**

sepidmahboobi@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University Of Medical Sciences

Full name of responsible person

Dr. Gholamreza Askari

Position

Ph.D of nutrition, Assistant Professor

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

Department of Community Nutrition School of Nutrition and Food Sciences Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 1792 2110

Fax**Email**

askari@mui.ac.ir

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

Isfahan University Of Medical Sciences

Full name of responsible person

Sepideh.Mahboobi

Position

MSc student of Nutrition

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Department of Community Nutrition School of Nutrition and Food Sciences Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

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Isfahan

Postal code**Phone**

+98 31 1792 2110

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