

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of probiotics on lipid profile, glycemic control and insulin levels, oxidative stress and inflammatory parameters in patients with type 2 diabetes

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 were enrolled with FBS \geq 126 mgr / dl and less than 15 years of their disease were over and the age range was 25 to 65 years. Elective subjects should not use replace treatments like Hormone 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: 40 patients with type 2 diabetes among people eligible to participate and referred to Motahari and Naderkazemi clinics in Shiraz, in the study was selected. Intervention: These patients were divided to either an intervention group (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 of experiment, fasting blood samples were tested again. Start and End Date of Intervention: 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: **IRCT201109197598N1**
Registration date: **2011-10-07, 1390/07/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-07, 1390/07/15

Registrant information

Name

Abbas Yousefinejad

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical sciences

Expected recruitment start date

2010-09-06, 1389/06/15

Expected recruitment end date

2010-11-06, 1389/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotics on lipid profile, glycemic control and insulin levels, oxidative stress and inflammatory parameters in patients with type 2 diabetes

Public title

Effect of probiotics on patients with type 2 diabetes

Purpose

Treatment

9/04/23422/پ/89/ص

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with diabetes type 2 were enrolled with FBS \geq 126 mgr / dl ; less than 15 years of their disease were over ; the age range was 25 to 65 years ; Elective subjects, next drugs prescribed by doctors, should be controlled the status of glucose and lipid levels and during the study could use of these drugs without changing in the prior dosage. Exclusion Criteria: Patients with diabetes type 2 that used replace treatments like Hormone or supplemental vitamin ; 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

N/A

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

Ethic Committee of Shiraz University of Medical sciences

Street address

Deputy of Researches and Technology, Shiraz University of Medical Sciences, Zand St, Shiraz, Iran

City

Shiraz

Postal code

713451978

Approval date

2010-08-12, 1389/05/21

Ethics committee reference number

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(×109 CFU) L. bulgaricus 600 million(×106 CFU) L. bifidum 600 million(×106 CFU) L. casei 1.2 billion(×109 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

Nader-Kazemi Clinic of Shiraz

Full name of responsible person

Mr. Ehsan Hosseinzadeh-hosseini

Street address

Nader-Kazemi Clinic, Vali-asr Square, Shiraz, Iran

City

Shiraz

2

Recruitment center

Name of recruitment center

Motahari Clinic of Shiraz

Full name of responsible person

Street address

Motahari Clinic, Nemazee Square, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Researches and Technology Deputy of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Hatam

Street address

Researches and Technology Deputy, Floor 7, Shiraz University of Medical Sciences, zand St, Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Researches and Technology Deputy of Shiraz 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

Tehran University of Medical sciences

Full name of responsible person

Abbas Yousefinejad

Position

Ph.D. Candidate in Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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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