Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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≥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

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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≥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

Specterophotometery

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

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/Assisstant Professor

Other areas of specialty/work

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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