Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effects of pro-biotic on inflammation factors in patients with type 2 diabetes mellitus

Protocol summary

Summary

Present study has been conducted to determine effect of probiotics on inflammation factors of patients with type II diabetes mellitus. Methods:This double-blind randomized, clinical trial study will be done on 44 type-2 diabetic patients, by available sampling. Patients were allocated to either case or control groups by permuted block randomization. Case group will receive one probiotic tablet and control group receive one placebo tablet daily for 8 weeks. At baseline and the end of study, 5 ml blood will be collected from each patient after a 14-h fasting in order to determine inflammation factors (CRP, TNF-α, IL-6) and serum lipid profile level. Dietary intake, anthropometric indices, blood pressure also were measured at baseline and the end of study. Data were analyzed by descriptive and analytic statistics. This study will show that probiotic supplementation is probably effective in risk factors for cardiovascular diseases in type 2 diabetes, via effect on serum lipid profile and inflammation factors.

General information

Acronym

CRP (C-reactive protein), IL6 (interleukin 6), TNF (tumor necrosis factor)

IRCT registration information

IRCT registration number: **IRCT2014110519816N1**
Registration date: **2015-02-03, 1393/11/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-03, 1393/11/14

Registrant information

Name

Bibi Leila Hoseini

Name of organization / entity

Sabzevar University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2015-01-17, 1393/10/27

Expected recruitment end date

2015-08-18, 1394/05/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of pro-biotic on inflammation factors in patients with type 2 diabetes mellitus

Public title

Pro-biotic on inflammation factors in patients with type 2 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients affected to diabetes melitus type 2; body mass index <35 kg/m2; patients enrolled in this study should have no infectious disease, hepatitis or renal diseases. Exclusion criteria: patients received cholesterol-lowering drugs, probiotic, prebiotic and omega-3 fatty acids and antibiotics from 1 month before

and during the study.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **44**

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
Sabzevar University of Medical Sciences

Street address
Sabzevar University of Medical Sciences- Sabzevar- Khorasan Razavi-

City
Sabzevar

Postal code

Approval date
2011-10-23, 1390/08/01

Ethics committee reference number
122.1696

Health conditions studied

1

Description of health condition studied
Type II diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Inflammation factors (CRP, IL-6 and TNF)

Timepoint
Baseline (before initiating intervention) and 8 weeks after initiating intervention

Method of measurement
Enzyme-like immune- sorbent assay (ELISA) kits (Monobind, Inc., Lake Forest, Calif., USA).

Secondary outcomes

1

Description
Serum lipid profile (LDL, HDL, total)

Timepoint
Baseline and the end of week 8

Method of measurement
Kits of Pars Test company and Auto analyzer Selectra 2 methods

Intervention groups

1

Description
supplementation tablet probiotic in intervention group: Each probiotic tablet is comprised of 100 mg Lactol probiotic. Lactol probiotic include Lactobacillus coagulans and Fructooligosaccharides (FOS). Lactol probitic is a product made by Bioplus Company of India which is under licence of Nature's American Company.

Category
Treatment - Drugs

2

Description
placebo in control group: Each placebo tablet contained farina. Placebo tablets were produced by Pharmaceutics department of Mashhad School of Pharmacy.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Clinic of Vasei Hospital in Sabzevar

Full name of responsible person
Tahere Tofighiyan

Street address
Diabete Department- Vasei Hospital- Tohid Shahr Bolvar- Sabzevar- Iran

City
Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Dr. Mohammad Mohammad Zade- Research Vice presidency

Street address
Vice presidency of Research and Technology- Sabzevar University of Medical Sciences- Sabzevra- Khorasan Razavi- Iran

City
Sabzevra

Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
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Position
Faculty member- MSc in midwifery

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