

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

Country

Iran (Islamic Republic of)

Phone

+98 51 4441 9573

Email address

hoseinil871@gmail.com

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 mellitus 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 probiotic 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- Sabzevar-
Khorasan Razavi- Iran

City

Sabzevara

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

Bibi Leila Hoseini

Position

Faculty member- MSc in midwifery

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

Sabzevar University of Medical Sciences- Sabzevar-
Khorasan Razavi-

City

Sabzevar

Postal code**Phone**

+98 51 4441 9573

Fax**Email**

hoseini1871@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Akram Kooshki

Position

Ph.D in Nutrition, Assistant Professor

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

Sabzevar University of Medical Sciences - Sabzevar-
Khorasan Razavi-

City

Sabzevar

Postal code**Phone**

+98 51 4441 9573

Fax**Email**

akooshki.nutr@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Bibi Leila Hoseini

Position

Faculty member of Sabzevar University of Medical
Sciences- Msc in midwifery

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

Sabzevar University of Medical Sciences- Sabzevar-
Khorasan Razavi- Iran

City

Sabzevar

Postal code**Phone**

+98 51 4441 9573

Fax**Email**

hoseini1871@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