

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of probiotic fermented milk on lipid profile, blood glucose, and hs-CRP levels in diabetic patients.

Protocol summary

Summary

Object: Determination the effect of probiotic fermented milk on lipid profiles, serum level of glucose and hs-CRP diabetic patients. Inclusion criteria: Person with diabetes, Ages 30 to 60 years. Exclusion criteria: not using cholesterol lowering drugs, not using anti inflammatory drugs, not using insulin therapy. 60 persons total(30 persons for each group). Intervention: probiotic fermented milk and current fermented milk. Duration of intervention: 2 months. The primary outcome or study outcoms: improvment of blood glucose level, lipid profile and hs-CRP level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307092017N14**
Registration date: **2013-09-07, 1392/06/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-07, 1392/06/16

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences & Tabriz Unversity

Expected recruitment start date

2011-04-18, 1390/01/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic fermented milk on lipid profile, blood glucose, and hs-CRP levels in diabetic patients.

Public title

Effect of probiotic fermented milk on lipid profile, blood glucose, and hs-CRP levels in diabetic patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: person with diabetes and aged between 30 to 60 years old. Exclusion criteria: not using cholesterol lowering drugs; not using anti inflammatory drugs; and not using insulin therapy.

Age

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

Not used

Assignment

Parallel

Other design features

There are two groups in this study. one group will consume probiotic fermented milk and other group will consume current fermented milk

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz university of medical sciences- Research vice chancellor

Street address

Tabriz university of medical sciences

City

Tabriz

Postal code

Approval date

2011-04-18, 1390/01/29

Ethics committee reference number

9287

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

lipid profiles

Timepoint

before intervention, 2 months after intervention

Method of measurement

By Laboratory kit

2

Description

blood glucose level

Timepoint

before intervention, 2 months after intervention

Method of measurement

by Laboratory kit

3

Description

hs-CRP

Timepoint

before intervention- 2 months after intervention

Method of measurement

By Laboratory Kit

Secondary outcomes

empty

Intervention groups

1

Description

Probiotic fermented milk (600 ml/day) duration of intervention: 8 weeks

Category

Other

2

Description

Current fermented milk (600 ml/day) duration of intervention: 8 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Community support of patients with diabetes

Full name of responsible person

Dr. Majid Mobaseri

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Tabriz- Faculty of nutrition

City

Tabriz

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University
Full name of responsible person
Dr. Akabar Taghizadeh
Street address
faculty of agriculture
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University
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
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Person responsible for updating data

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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