

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effects of consumption of probiotic yoghurt and conventional yoghurt on blood sugar, lipid profile, oxidative stress parameters and inflammatory marker in type 2 diabetic patients.

Protocol summary

Summary

The aim of this randomized double blind clinical trial is to determine the effects of probiotic yoghurt consumption on some blood biochemical parameters in type 2 diabetic patients. Sixty patients aged between 30-60 years old from both sexes are assigned into two groups. Patients in intervention group consume 300 gr/day probiotic yoghurt and patients in control group consume 300 gr/day conventional yoghurt for 6 weeks. Anthropometric and blood pressure measurements, 3-day 24h dietary recalls and fasting blood samples are collected at the beginning and at the end of study. Fasting blood sugar, glycosylated hemoglobin, insulin, lipid profile, malondialdehyde (MDA), total antioxidant capacity (TAC), catalase, superoxide dismutase, glutathione peroxidase and hsCRP are measured. LDL and HOMA-IR are calculated by formula. The participants are asked not to change their regular diet, medicine and activity during the study and not to consume any other yoghurt.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903223533N1**

Registration date: **2010-07-03, 1389/04/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-07-03, 1389/04/12

Registrant information

Name

Javad Mohtadina

Name of organization / entity

Faculty of health and nutrition

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences, Iran Dairy Industries Company

Expected recruitment start date

2010-05-31, 1389/03/10

Expected recruitment end date

2010-07-12, 1389/04/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of consumption of probiotic yoghurt and conventional yoghurt on blood sugar, lipid profile, oxidative stress parameters and inflammatory marker in type 2 diabetic patients.

Public title

The effects of probiotic yoghurt on type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having type 2 diabetes, 30 to 60 years old, LDL level more than 100 mg/DI Exclusion criteria: having the renal or hepatic failure, cardiovascular disease, inflammatory bowel disease, thyroid disorders

and lactose intolerance, treatment with insulin and taking corticosteroids, NSAIDS, immunosuppressives, cholesterol lowering drugs, multivitamin-mineral and fiber supplements, BMI more than 35 Kg/m2, smoking, pregnancy and lactation, use of multivitamin-mineral and fiber supplements 3 weeks prior to the study, use of antibiotics 1 month the study and during the study, having acute gastrointestinal disorders 1 month prior to the study and during the study

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golbad Ave

City

Tabriz

Postal code

Approval date

2010-05-31, 1389/03/10

Ethics committee reference number

897

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

hsCRP

Timepoint

baseline and after 6 weeks

Method of measurement

immunoturbidometry

2

Description

Fasting Blood Sugar

Timepoint

baseline and after 6 weeks

Method of measurement

spectrophotometry

3

Description

Hemoglobin A1c

Timepoint

baseline and after 6 weeks

Method of measurement

Chromatography

4

Description

Insulin

Timepoint

baseline and after 6 weeks

Method of measurement

ELIZA

5

Description

HOMA-IR

Timepoint

Baseline and after 6 weeks

Method of measurement

Formula

6

Description

Total Cholesterol

Timepoint

Baseline and after 6 weeks

Method of measurement

Spectrophotometry

7

Description

Triglyceride

Timepoint

Baseline and after 6 weeks

Method of measurement

Spectrophotometry

8

Description

HDL

Timepoint

Baseline and after 6 weeks

Method of measurement

Spectrophotometry

9

Description

LDL

Timepoint

Baseline and after 6 weeks

Method of measurement

Friedewald Formula

10

Description

Malondialdehyde

Timepoint

Baseline and after 6 weeks

Method of measurement

Spectrophotometry

11

Description

Catalase

Timepoint

Baseline and after 6 weeks

Method of measurement

Hugo Aebi Method

12

Description

Glutathione peroxidase

Timepoint

Baseline and after 6 weeks

Method of measurement

Spectrophotometry

13

Description

Superoxide dismutase

Timepoint

Baseline and after 6 weeks

Method of measurement

Spectrophotometry

14

Description

Total Antioxidant Capacity (TAC)

Timepoint

Baseline and after 6 weeks

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Baseline and after 6 weeks

Method of measurement

Formula

2

Description

Dietary Factors

Timepoint

Baseline and after 6 weeks

Method of measurement

3-day 24h dietary recalls

3

Description

Blood Pressure

Timepoint

Baseline and after 6 weeks

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Intervention Group:Probiotic Yoghurt,300 gr/day,6 weeks

Category

Treatment - Drugs

2

Description

Control Group:Conventional Yoghurt,300 gr/day,6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Endocrine Clinic

Full name of responsible person

Dr Javad Mohtadi Nia

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Javad Mohtadi Nia

Street address

Golbad street

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

Iran Dairy Industries Company

Full name of responsible person

Ali Akbarian Moghari

Street address

Africa Boulevard

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran Dairy Industries Company

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

Faculty of Health and Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

Dr Javad Mohtadi Nia

Position

Associate Professor in Department of Food Science and Technology

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Hanie Sadat Ejtahed

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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