

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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)

##### Phone

+98 41 1335 7581

##### Email address

mohtadinaj@tbzmed.ac.ir

##### 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

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

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**Fax****Email**

Mohtadiniaj@tbzmed.ac.ir,Haniejtahed@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hanie Sadat Ejtahed

**Position**

MSc Student of Nutrition Science

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## Person responsible for updating data

#### Contact

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**Postal code**

**Phone**

+98 41 1335 7580

**Fax****Email**

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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*