

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effects of consumption of Lactobacillus Casei on glycemic factors, and serum sirtuin1 and fetuin-A levels in type 2 diabetic patients: A controlled clinical trial.

#### Protocol summary

##### Summary

The aim of present study is evaluating the effect of Lactobacillus Casei on glycemic factors, and serum sirtuin1 and fetuin-A levels in type 2 diabetic patients. In this randomized double blind placebo control study 44 diabetic patient will be selected and randomly assigned into intervention and control groups, each containing 22 subjects. Patients in intervention group will receive probiotic capsules containing 108cfu Lactobacillus Casei and patients in control group will receive placebo capsules daily for 2 months. Inclusion criteria: patients who are diagnosed with type2 diabetes more than a year ago; patients aged 30 to 50 years. Exclusion criteria: Insulin injection, body mass index over 35 kg/m2, infectious and inflammatory diseases, use of antibiotics and anti-inflammatory drugs a month before and/or during intervention. The anthropometric measurements, glycemic factors, and serum sirtuin1 and fetuin-A levels will be measured before and after the intervention. Then the results will be compared and discussed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201607034105N17**

Registration date: **2016-08-14, 1395/05/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-08-14, 1395/05/24

##### Registrant information

###### Name

Beit Allah Alipour

##### Name of organization / entity

Health & Nutrition Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

alipourb@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Department of Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-09-05, 1395/06/15

##### Expected recruitment end date

2016-11-05, 1395/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of consumption of Lactobacillus Casei on glycemic factors, and serum sirtuin1 and fetuin-A levels in type 2 diabetic patients: A controlled clinical trial.

##### Public title

The effects of consumption of Lactobacillus Casei on diabetes control

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with diabetes for more than a year of developing diabetes and over 6 months pass the use of glucose lowering drugs ; Age 30 to 50 years.

Exclusion criteria: Insulin injections; BMI > 35 Kg / m<sup>2</sup>; smoking; breastfeeding and pregnancy; menopause; using antibiotics and anti-inflammatory drugs within a month before and during the intervention; chronic digestive problems, and acute gastrointestinal problems within a month before and during the intervention; infectious and inflammatory diseases; Get any supplements.

**Age**

From **65 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**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**

Tabriz University of Medical Sciences

**Street address**

Tabriz/ Azady St./ Ghol-Ghasht Ave.

**City**

Tabriz

**Postal code**

5166614711

**Approval date**

2016-07-25, 1395/05/04

**Ethics committee reference number**

IR.TBZMED.REC.1395.402

**Health conditions studied****1****Description of health condition studied**

Diabetes Mellitus

**ICD-10 code**

E11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

**Primary outcomes****1****Description**

Fasting Blood Sugar

**Timepoint**

before intervention and after 2 months intervention

**Method of measurement**

Spectrophotometry

**2****Description**

HbA1c

**Timepoint**

before intervention and after 2 months intervention

**Method of measurement**

Column chromatography

**3****Description**

Insulin Resistance

**Timepoint**

before intervention and after 2 months intervention

**Method of measurement**

homeostasis model (HOMA-IR)

**4****Description**

Serum Fetuin-A

**Timepoint**

before intervention and after 2 months intervention

**Method of measurement**

ELISA technique

**5****Description**

serum sirtuin1

**Timepoint**

before intervention and after 2 months intervention

**Method of measurement**

ELISA technique

**Secondary outcomes****1****Description**

Height and Weight

**Timepoint**

Before Intervention and After 2 Months Intervention

**Method of measurement**

Digital scale and stadiometer

## 2

### Description

Food Intake

### Timepoint

Before Intervention, Middle of the Intervention, and After Intervention

### Method of measurement

24-hour dietary recalls questionnaire

## Intervention groups

### 1

#### Description

Placebo capsules Patients in control group will receive placebo capsules daily for two months.

#### Category

Placebo

### 2

#### Description

Probiotic Capsules Containing Lactobacillus Casei Patients in intervention group will receive one capsule containing 108cfu Lactobacillus Casei daily for two months. Capsules should be taken with food and a glass of water.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Endocrinologist Office Located in the Sheykholraees Clinic

##### Full name of responsible person

Dr. Ismail Faraji - Endocrinologist, Department of Faculty of Medicine

##### Street address

Tabriz, Azadi St., Sheykholraees Clinic, Dr.Ismail Faraji's office

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Department of Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Rashidi, Research Assistant of Tabriz University of Medical Sciences

##### Street address

Tabriz- Azadi St.- Ghol-Ghasht Ave.

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research Department of Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Leila Khalili

##### Position

MSc. Student of Nutrition

##### Other areas of specialty/work

##### Street address

Tabriz- Azadi St.- Ghol-Ghasht Ave.

##### City

Tabriz

##### Postal code

##### Phone

+98 41 3335 7581

##### Fax

##### Email

leylakhalili1990@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Leila Khalili

##### Position

MSc. Student of Nutrition

##### Other areas of specialty/work

##### Street address

Tabriz- Azadi St.- Ghol-Ghasht Ave.

##### City

Tabriz

##### Postal code

##### Phone

+98 41 3335 7581

##### Fax

**Email**

leylakhali1990@gmail.com

**Web page address****Email**

leylakhali1990@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Leila Khalili

**Position**

MSc. Student of Nutrition

**Other areas of specialty/work****Street address****City****Postal code****Phone**

00

**Fax****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*