Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 / m2; 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 Mallitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting Blood Sugar

Timepoint
befor intervention and after 2 monthes intervention

Method of measurement
Spectrophotometry

2

Description
HbA1c

Timepoint
befor intervention and after 2 monthes intervention

Method of measurement
Column chromatography

3

Description
Insulin Resistance

Timepoint
befor intervention and after 2 monthes intervention

Method of measurement
homeostasis model (HOMA-IR)

4

Description
Serum Fetuin-A

Timepoint
befor intervention and after 2 monthes intervention

Method of measurement
ELISA technique

5

Description
serum sirtuin1

Timepoint
befor intervention and after 2 monthes intervention

Method of measurement
ELISA technique

Secondary outcomes

1

Description
Height and Weight

Timepoint
Before Intervention and After2 Monthes 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.
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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
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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