Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of soy milk containing lactobacillus plantarum A7 on inflammatory indices, lipid profile and physical activity in type 2 diabetic patients with nephropathy

Protocol summary

Summary

The current study is a randomized, double-blind, placebo-controlled trial to evaluate the effect of soy milk containing lactobacillus plantarum A7 on inflammatory indices and lipid profile in type 2 diabetic patients with nephropathy. The subjects consist of volunteers with T2DM, who have micro or macro-albuminuria and their GFR is higher than 60 ml/min, they also must not consume any vitamin, mineral or omega-3 supplements 3 weeks before beginning of the trial and during it. Reasons for excluding people from our study are: not adhering to the administrated diet, occurrence of other kidney diseases, cardiac ischemia, gastrointestinal, hepatic or thyroid diseases and acute infections. At the beginning of the study 40 subjects with the abovementioned criteria, will be randomly allocated to the intervention or control groups where they will receive 200 ml/day of soy milk containing L.plantarum or soy milk for 8 weeks. To evaluate the effects of the intervention, serum creatinine, proteinuria, IL-18, serum sialic acid, TNF-α, hsCRP, GFR and lipid profile of the serum will be measured at baseline and after the intervention period and the results will be used to evaluate the probable effectiveness of the intervention to help diabetic patients with nephropathy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601027479N2**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of soy milk containing lactobacillus plantarum A7 on inflammatory indices, lipid profile and physical activity in type 2 diabetic patients with nephropathy

Public title

Effect of probiotic supplementation on diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having T2DM ;having micro or macro albuminuria ;GFR higher than 60 ml/min ;not having hepatic gastrointestinal and thyroid diseases ;not having rheumatoid arthritis ;not having any kind of allergy or acute infection ;not consuming vitamin mineral or omega-3 supplements 3 weeks before beginning of the trial and during the trial ;not consuming antibiotics 1 month before the trial and during the trial ;absence of pregnancy or lactating ;not smoking ;not having any specific diet. Exclusion criteria: Not adhering to the administrated diet ;occurrence of other kidney diseases ;cardiac ischemia ;gastrointestinal ;hepatic or thyroid diseases ;acute infection ;needing to be dialysed ;undergoing kidney transplantation ;any kind of surgery or occurrence of pregnancy ;starting to consume drugs that may affect protein excretion such as NSAIDs or ACE-I.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan.

City

Isfahan

Postal code

Approval date

2015-11-02, 1394/08/11

Ethics committee reference number

IR.MUI.REC.1394.3.620

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

E11.21

ICD-10 code description

Glomerular disorders in diabetes mellitus

Primary outcomes

1

Description

Serum creatinine

Timepoint

Before the intervention and 2 months after beginning of the intervention

Method of measurement

mg/dl , biochemical analysis

2

Description

Proteinuria

Timepoint

Before the intervention and 2 months after beginning of the intervention

Method of measurement

mg/day, Biochemical analysis

3

Description

IL-18

Timepoint

Before the intervention and 2 months after beginning of the intervention

Method of measurement

ρg/ml , ELISA

4

Description

Serum sialic acid

Timepoint

Before the intervention and 2 months after beginning of the intervention

Method of measurement

mmol/l , ELISA

5

Description

TNF-α

Timepoint

Before the intervention and 2 months after beginning of the intervention

Method of measurement

ρg/ml , ELISA

6

Description
hsCRP
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl , ELISA

7

Description
GFR
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
ml/min , calculation

8

Description
Serum cholestrol
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl , biochemical analysis

9

Description
Serum triglyceride
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl , biochemical analysis

10

Description
Serum LDL-C
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl , biochemical analysis

11

Description
Serum HDL-C
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl , biochemical analysis

12

Description
Physical activity
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
Met-h/wk , Questionnaire

Secondary outcomes

1

Description
Serum sodium
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl ,flame photometry

2

Description
Serum potassium
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl ,flame photometry

3

Description
Fasting blood sugar
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
mg/dl , Biochemical analysis

4

Description
Serum genistein
Timepoint
Before the intervention and 2 months after beginning of the intervention
Method of measurement
nmol/l , TR-FIA

Intervention groups

1

Description
Soy milk containing lactobacillus plantarum A7, 200 cc orally, once a day for 2 months
Category
Treatment - Other

2

Description
Soy milk without lactobacillus plantarum A7 , 200 cc

orally, once a day for 2 months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and metabolism research center

Full name of responsible person

Behnood Abbasi

Street address

Isfahan University of Medical Sciences, Hezarjarib street, Isfahan.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Yahai

Street address

Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan.

City

Isfahan

Grant name

Grant code / Reference number

394620

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

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Behnood Abbasi

Position

Ph.D. Student

Other areas of specialty/work

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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