

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Assessment of the effect of probiotic supplement and soy milk on lipid profiles, Blood sugar, insulin resistance status and blood pressure in diabetic patients type II

Protocol summary

Summary

Diabetes mellitus is the most common chronic metabolic diseases in both developing and developed countries. Soy products can have beneficial effects on metabolic disorders. The purpose of this study is to investigate the effect of soy milk and probiotic capsule together on the lipid profile, blood sugar, blood pressure and insulin resistance status in patients with diabetes type II. This study is a controlled randomized, clinical trial with placebo which was performed on 100 patients, aged 40-75 years old, they will be excluded from the study in case of having any acute and chronic disease. Patients were randomly divided into 4 recipient groups: 1- soy milk + probiotic supplement 2- soy milk + placebo 3- milk + placebo 4 - probiotic capsules and will receive a glass of milk (240 ML) and a capsule every day for 6 weeks. Then the weight changes, blood pressure, fasting blood sugar, lipid profile and insulin are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080423495N1**
Registration date: **2016-01-22, 1394/11/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name

Azime Hasan poor

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 3762 2725

Email address

h.nutritionist@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of probiotic supplement and soy milk on lipid profiles, Blood sugar, insulin resistance status and blood pressure in diabetic patients type II

Public title

the effect of probiotic supplement and soy milk in diabetic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : having willingness to cooperate in the plan and presenting the written consent form ; being 75-40 years old ; diagnosis of diabetes based on a specialist opinion ; being residence of Fars province ; having the ability to understand the objectives of the

study Exclusion criteria : any acute and chronic disease that cause patients not to be able to follow research protocols ; consumption of foods and products that contain probiotic bacteria 3 weeks before the start of the intervention and during the intervention ; Change in dose of drug or insulin ; using drugs that lower the blood sugar ; blood pressure and blood fat during the intervention ; use of antibiotics ; the incidence of severe side effects and failure to follow the diet ; non-compliance with the study protocol.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Postal code

Approval date

2015-07-12, 1394/04/21

Ethics committee reference number

IR.SUMS.REC.1394.62

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10, E11,

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

fasting blood sample

Timepoint

The beginning and end of the intervention

Method of measurement

measured by enzymatic spectrophotometry analysis

2

Description

blood pressure

Timepoint

Early intervention-Every tree weeks, once-End of intervention

Method of measurement

mmHg,with an automatic sphygmomanometer

3

Description

lipid profile

Timepoint

The beginning and end of the intervention

Method of measurement

measured by enzymatic spectrophotometry analysis

4

Description

weight

Timepoint

Early intervention-Every tree weeks, once-End of intervention

Method of measurement

seca Scale

5

Description

insulin

Timepoint

The beginning and end of the intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

body mass index

Timepoint

The beginning and end of the intervention

Method of measurement

Measured height and weight

2

Description

insulin resistant

Timepoint

The beginning and end of the intervention

Method of measurement

HOMA-IR

Intervention groups

1

Description

Intervention group: soy milk+probiotic cap , a glass of milk (and a capsule every day for 6 weeks

Category

Treatment - Other

2

Description

Intervention group: soy milk+placebo cap , a glass of milk and a capsule every day for 6 weeks

Category

Treatment - Other

3

Description

Intervention group: probiotic cap , a capsule every day for 6 weeks

Category

Treatment - Other

4

Description

Control group ;milk + placebo , a glass of milk and a capsule every day for 6 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Dr Siavash Babajafari

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

Street address

Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Shiraz 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

Shiraz University Of Medical Sciences

Full name of responsible person

Dr Siavash Babajafari

Position

Nutrition Phd

Other areas of specialty/work

Street address

Kooye Zahra

City

Shiraz

Postal code

Phone

+98 71 3725 1001

Fax

Email

jafaris@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Dr Siavash Babajafari

Position

Nutrition Phd

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

Kooye Zahra

City

Shiraz

Postal code**Phone**

+98 71 3725 1001

Fax**Email**

jafaris@sums.ac.ir

Web page address

Eram Street

City

Shiraz

Postal code**Phone**

+98 77 3762 2725

Fax**Email**

h.nutritionist@yahoo.com

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

Shiraz University Of Medical Sciences

Full name of responsible person

Azime Hasan poor

Position

Postgraduate Student

Other areas of specialty/work**Street 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*