Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of soy milk containing probiotics on promoter methylation and DNA damage among type-2 diabetic patients

Protocol summary

Summary

In this study the effect of probiotics in gene expression which are effective in oxidative reduction will be studied and as regard promoter changes like adding methyl group have important role in the increase or decrease of gene expression, therefore; we will measure the promoter methylation of two important genes. In this study we will select 40 patients with type 2 diabetes, between 25-75 years old, without other diseases like heart disease, liver, and infection. According to evidence probiotic supplement can be more effective in the treatment of disease so we will fortify soymilk, as a substrate for these bacteria, with probiotics. Soymilk will fortify with Lactobacillus plantarum E7 in the concentration of 100000000 and will be consume for 8 weeks by patients. Before and after 8 weeks we will measure promoter methylation for MLH1 and MSH2, serum concentration of 8-oxo-2-deoxogovanosine, and superoxide dismutase activity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405265062N8**
Registration date: **2014-09-16, 1393/06/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-16, 1393/06/25

Registrant information

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Recruitment status
Recruitment complete

Funding source
Isfahan University Of Medical Sciences

Expected recruitment start date
2014-03-20, 1392/12/29

Expected recruitment end date
2014-10-22, 1393/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of soy milk containing probiotics on promoter methylation and DNA damage among type-2 diabetic patients

Public title
The effect of probiotic soy milk in the treatment of type 2 diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patient with type 2 diabetes; between 25-75 years old; no consumption of vitamin supplement; antioxidants; mineral; omega-3 since 3 weeks ago.
Exclusion criteria: smokers; pregnant and lactating women; patients with liver disease; IBS; thyroid disease; Rheumatoid arthritis; infection; heart diseases; sever infection; disobedience of recommended diet

Age

From **25 years** old to **75 years** old

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 Science

Street address

Isfahan University of Medical Science, Hezarjarib street, Isfahan

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Postal code

Approval date

2014-06-22, 1393/04/01

Ethics committee reference number

393150

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

MLH1 promoter methylation

Timepoint

Before and after intervention

Method of measurement

MethyQESD method

Secondary outcomes

1

Description

Serum concentration of 8-Oxo-2'-deoxyguanosine

Timepoint

Before intervention and after eighth week

Method of measurement

Eliza method

2

Description

MSH2 promoter methylation

Timepoint

Before intervention and after eighth week

Method of measurement

methyQESD method

3

Description

The activity of superoxide reductase

Timepoint

Before intervention and after eighth week

Method of measurement

Eliza method

Intervention groups

1

Description

Intervention group will consume probiotic soy milk containing 100000000 lactobacillus bacteria for 8 weeks.

Category

Prevention

2

Description

control group: In this group soy milk without probiotic will consume for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Metabolic and Endocrine Research Center

Full name of responsible person

Mitra Hariri

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University Of Medical Sciences
Full name of responsible person
Peyman Adibi
Street address
Isfahan University of Medical Sciences, Hezarjarib street, Isfahan
City
Isfahan
Grant name
Grant code / Reference number
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

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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