

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of soy-milk and cow milk consumption on inflammatory factors, cardiovascular factors ,renal factors, fibrinolytic indice and oxidative stress among type-2 diabetic patients with nephropathy stage 1 and 2

Protocol summary

Summary

We evaluated the effects of soy milk compared to cow's milk on inflammation, oxidative stress, fibrinolytic markers and cardiorenal risk factors among type 2 diabetic patients with nephropathy. Having allergy to soy product or cow's milk and incidence of chronic or acute diseases were exclusion criterias. There were two trial periods for four weeks (soy milk period with diet containing 0.8 g/kg protein and cow's milk period diet containing 0.8 g/kg protein) and a washout period for 2 weeks. In the soy milk period only one glass of soy milk (240 cc) was replaced instead of one glass of cow's milk (240 cc). In this research antropometric Indicators, inflammatory, oxidative stress and fibrinolytic markers, renal function indices, blood pressure, lipid profiles, and glycemic control indice evaluated after soy milk period and cow's milk period . This study administrated for 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105282839N2**

Registration date: **2011-09-06, 1390/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-06, 1390/06/15

Registrant information

Name

Leila Azadbakht

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Esfahan university of medical sciences

Expected recruitment start date

2010-09-06, 1389/06/15

Expected recruitment end date

2011-09-06, 1390/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of soy-milk and cow milk consumption on inflammatory factors, cardiovascular factors ,renal factors, fibrinolytic indice and oxidative stress among type-2 diabetic patients with nephropathy stage 1 and 2

Public title

Effect of soy-milk consumption on inflammatory factors, cardiovascular factors ,renal factors, fibrinolytic indice and oxidative stress

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included adults with (>18y old) diagnosis of type 2 diabetes nephropathy (diabetic subjects that had proteinuria more than 300 mg/day and had GFR more than 90 mL/min); Not having allergy to soy product or cow's milk. exclusion criteria included diabetic nephropathy patients that they were pregnant or lactation women; changing dosage of oral hypoglycemic agents or lipid-lowering medications; alcohol and cigarette consumption; allergy or intolerance to soybeans or milk ;presence of breast malignant and Not following the research protocol.

Age

From **28 years** old to **81 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2011-02-20, 1389/12/01

Ethics committee reference number

189051

Health conditions studied

1

Description of health condition studied

diabetic nephropathy

ICD-10 code

n08.3

ICD-10 code description

Glomerular disorders in diabetes mellitus

Primary outcomes

1

Description

soymilk

Timepoint

at baseline and 4,6,10 weeks

Method of measurement

dietary record

Secondary outcomes

1

Description

HbA1c

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

2

Description

creatinin

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

3

Description

total cholesterol

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

4

Description

insulin

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

5

Description

systolic blood pressure

Timepoint

at 1,4,6,10 weeks

Method of measurement

Blood Pressure Monitor

6

Description

diastolic blood pressure

Timepoint

at 1,4,6,10 weeks

Method of measurement

Blood Pressure Monitor

7

Description

Malondialdehyde

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

8

Description

fibrinogen

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

9

Description

Urine creatinine

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

10

Description

urine protein

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

11

Description

BUN

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

12

Description

TNF- α

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

13

Description

IL6

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

14

Description

FBS

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

15

Description

TG

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

16

Description

hs-CRP

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

17

Description

d-dimer

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

18

Description

HDL

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

19

Description

LDL

Timepoint

at 1,4,6,10 weeks

Method of measurement

biochemical analysis

Intervention groups

1

Description

In this randomized crossover design, for 4 weeks , one group consumption cows milk one glass every day .

Category

Other

2

Description

Other group consumptin cow milk 1 glass every day for 4 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

alzahra hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Leila Azadbakht

Street address

Department of Community Nutrition, School of Nutrition and Food Science, Isfahan University of Medical Sciences,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

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Leila Azadbakht

Position

Associate Prof.

Other areas of specialty/work

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Full name of responsible person

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Position

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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