Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 caw'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 caw'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 caw'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 caw'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 caw'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 diabetics nephropathy (diabetics subjects that had proteinuria more than 300 mg/day and had GFR more than 90 mL/min); Not having allergy to soy product or caw’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 commeitee 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 و 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
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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

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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