

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 glycemc 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

Nutrition department, School of health, Isfahan University of Medical Sciences, Isfahan, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2719

##### Email address

azadbakht@hlth.mui.ac.ir

##### 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- $\alpha$

### **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

#### Street address

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

#### City

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#### Postal code

#### Phone

+98 31 1792 2719

#### Fax

#### Email

Azadbakht@hlth.mui.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Dr Leila Azadbakht

#### Position

Associate Proffesor

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

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#### Name of organization / entity

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**Email**

Azadbakht@hlth.mui.ac.ir

**Web page 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*