

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effects of isoflavones on cardiovascular disease risk factors and bone metabolism markers in peritoneal dialysis patients

Protocol summary

Study aim

The aim of this double-blind randomized clinical trial is to determine the effects of isoflavones on cardiovascular disease risk factors and bone metabolism markers in peritoneal dialysis patients.

Design

This study is a double-blind, randomized controlled clinical trial with two parallel groups. 50 patients will be randomly assigned into isoflavone and control group.

Settings and conduct

Patients under peritoneal dialysis referring to the Shafa clinic and Dr. Najafi clinic will be invited to participate. After assessing the entrance criteria, 7 cc blood samples are taken. The food recall is completed. Supplements are given to patients for a month. For double-blind implementation, in the beginning, all boxes of supplements by a third party is coded as A and B

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 6 months have passed since the onset of Continuous Ambulatory Peritoneal Dialysis; Being in the age range of 18-75 years Exclusion criteria: Receiving isoflavones supplement

Intervention groups

Patients in the isoflavone group will receive, for 8 weeks, two tablets of Soyagol (Goldaru Company) per day, each containing 50 mg of soy isoflavone. Patients in the control group will receive 2 tablets of placebo containing starch (Goldaru Company) per day.

Main outcome variables

Serum concentrations of lipoprotein-a; malondialdehyde; high sensitivity c-reactive protein; Soluble intercellular adhesion molecule-1; Soluble vascular adhesion molecule-1; E-selectin; bone alkaline phosphatase; osteocalcin; N-telopeptide; osteoprotegerin; Receptor activator of nuclear factor kappa-B ligand; Intact parathyroid hormone; triglyceride; total cholesterol; High-density lipoprotein cholesterol; low-density lipoprotein cholesterol; albumin; calcium; phosphorous; blood nitrogen urea; creatinine

General information

Reason for update

changes in some outcome variables

Acronym

IRCT registration information

IRCT registration number: **IRCT20181120041710N1**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-28, 1398/09/07**

Update count: **1**

Registration date

2019-01-10, 1397/10/20

Registrant information

Name

Zahra Yari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7484

Email address

zahrayari_nut@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-28, 1397/09/07

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of isoflavones on cardiovascular disease risk factors and bone metabolism markers in peritoneal dialysis patients

Public title

Effect of isoflavones supplementation in peritoneal dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Continuous Ambulatory Peritoneal Dialysis for 6 months or more Body mass index (BMI) below 35

Exclusion criteria:

Infectious diseases (especially peritonitis) and inflammatory diseases Liver diseases Past medical history of cancer Receiving glucocorticoid drugs, non-steroidal anti-inflammatory drugs Receiving isoflavone supplements Constant consumption of soy or foods containing soy in the diet

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients on the basis of diabetes are categorized and are randomly assigned to the soy isoflavone or placebo group. To random allocation, a Stratified Blocked Randomization method is used. After specifying blocks of size 4 and allocating numbers to each block, a random number table is used to determine the treatment assignment list. Randomization is concealed in sequentially numbered, sealed, opaque envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind (investigators and patients) trial. For double-blind implementation, at the beginning of the study, all boxes containing soybean isoflavone or placebo by a third party (someone other than the researchers) is coded as A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of National Nutrition and Food Technology Research Institute

Street address

No. 46, West Arghavan St., Farahzadi Blv., Shahrak Qods,

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1397.001

Health conditions studied

1

Description of health condition studied

peritoneal dialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Serum concentrations of lipoprotein(a) [Lp (a)]

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kit

2

Description

Serum concentrations of malondialdehyde (MDA)

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kit

3

Description

Serum concentrations of high sensitivity c-reactive protein (hs-CRP)

Timepoint

Before the intervention and 8 weeks after the

intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kit

4

Description

Serum concentrations of Soluble intercellular adhesion molecule-1 (sICAM-1)

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kit

5

Description

Serum concentrations of bone alkaline phosphatase

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

6

Description

Serum concentrations of Osteocalcin

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

7

Description

Serum concentrations of N-telopeptide

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

8

Description

Serum concentrations of Osteoprotegerin

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

9

Description

Serum concentrations of Receptor activator of nuclear factor kappa-B ligand (RANKL)

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

10

Description

Serum concentrations of Intact parathyroid hormone (iPTH)

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

11

Description

Serum concentrations of triglyceride

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzymatic assay kit

12

Description

Serum concentrations of total cholesterol

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzymatic assay kit

13

Description

Serum concentrations of High-density lipoprotein cholesterol (HDL-C)

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzymatic assay kit

14

Description

Serum concentrations of low-density lipoprotein cholesterol (LDL-C)

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzymatic assay kit

15

Description

soluble vascular cellular adhesion molecule-1

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

16**Description**

E-selectin

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes**1****Description**

Serum concentrations of albumin

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzymatic assay kit

2**Description**

Serum concentrations of calcium

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Colorimetric method using autoanalyzer

3**Description**

Serum concentrations of phosphorous

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Colorimetric method using autoanalyzer

4**Description**

blood nitrogen urea

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Colorimetric method

5**Description**

creatinine

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Colorimetric method

Intervention groups**1****Description**

Intervention group: isoflavone supplementation: they will receive, for 8 weeks, two tablets of Soyagol (Goldaru Company) per day, each containing 50 mg of soy isoflavone.

Category

Treatment - Other

2**Description**

Control group: they will receive 2 tablets of placebo containing starch (Goldaru Company) per day for 8 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shafa Clinic

Full name of responsible person

Shahnaz Atabak

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Email

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2**Recruitment center****Name of recruitment center**

Dr.najafi's Clinic

Full name of responsible person

Iraj Najafi

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6162365224

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Nutrition and Food Technology Research
Institute

Full name of responsible person
Esmat Naseri

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Email
Nasseri_esm@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
National Nutrition and Food Technology Research
Institute

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Zahra Yari

Position
Ph.D candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Latest degree
Master

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable