

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of isoflavones on hypertension, serum concentrations of fructoseamine and advanced glycated end products 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 hypertension, serum concentrations of glucose, fructoseamine and advanced glycated end products in peritoneal dialysis patients

Design

This study is a double-blind, randomized controlled clinical trial with two parallel groups. 44 patients will be randomly assigned into isoflavone and control group.

Settings and conduct

Patients under peritoneal dialysis referring to the peritoneal dialysis unit of Shafa clinic are invited to participate in this research, and the research goals and method will be explained for them. 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

Participants/Inclusion and exclusion criteria

Inclusion criterion: Continuous Ambulatory Peritoneal Dialysis for 6 months or more. Body mass index below 35
Exclusion criteria: infections; inflammatory diseases; liver diseases; past medical history of cancer; receiving glucocorticoid and anti-inflammatory drugs, receiving isoflavone supplements, Constant consumption of soy or foods containing soy in the diet

Intervention groups

Patients in the isoflavone group 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 also receive 2 tablets of placebo containing starch (Goldaru Company) per day for 10 weeks.

Main outcome variables

Serum concentrations of glucose, fructoseamine, carboxymethyl lysine, pentosidine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091116002716N4**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-23, 1398/10/02**

Update count: **1**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Hadi Tabibi

Name of organization / entity

Department of Human Nutrition, Faculty of Nutrition Sciences and Food Technology, Shahid Beheshti Uni

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 7424

Email address

nsft@hbi.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-16, 1398/08/25

Expected recruitment end date

2020-01-23, 1398/11/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of isoflavones on hypertension, serum concentrations of fructoseamine and advanced glycated end products in peritoneal dialysis patients

Public title

Effects of isoflavones in peritoneal dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

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

Exclusion criteria:

infections; inflammatory diseases liver diseases past medical history of cancer receiving glucocorticoid and anti-inflammatory drugs receiving isoflavone supplements Constant consumption of soy or foods containing soy in the diet

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation is Stratified Blocked Randomization (based on diabetes mellitus). The unit of allocation is the individual people. Investigators will be blind to group allocation.

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 Shahid Beheshti University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code

1381619573

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1397.038

Health conditions studied**1****Description of health condition studied**

End stage of renal disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

Serum concentrations of glucose

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Enzymatic method

2**Description**

Serum concentrations of fructoseamine

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

3**Description**

Serum concentrations of carboxymethyl lysine

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

4**Description**

Serum concentrations of pentosidine

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

5**Description**

Systolic blood pressure

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

mercury sphygmomanometer

6**Description**

Diastolic blood pressure

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

mercury sphygmomanometer

Secondary outcomes

empty

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

Intervention group: Patients in the isoflavone group 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: Patients in the control group will also 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

Street address

No 42, Hosseini Ave., Valiasr Square

City

Tehran

Province

Tehran

Postal code

6182965723

Phone

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Email

Info@irankf.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr. Esmat Naseri

Street address

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

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nutrition@sbm.ac.i

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

Faculty of Nutrition and Food Technology, Shahid
Beheshti medical university

Full name of responsible person

Dr. Hadi Tabibi

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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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