Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 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
+98 21 8889 6051
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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Tehran
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Postal code
1981619573
Phone
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Email
nutrition@sbmu.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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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