Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of herbal extracts (Punica Granatum) on weight and cachexia indices in peritoneal dialysis patients

Protocol summary

Study aim
Improvement in weight indices; cachexia and laboratory indices after using herbal extracts (Punica Granatum) syrup

Design
A concealed, randomized, not blinded, sham-controlled clinical trial with a parallel-group design of 60 patients, block randomization was used for randomization.

Settings and conduct
Determining 30 persons for control group and 30 for consumer group, 5ml three times a day before food for at least 2 months, checking the patient's acceptance during the study, recording the patient's demographic information, measuring the patient's weight with scale at the beginning, one and two months after the start of treatment and measuring other indicators according to laboratory standards.

Participants/Inclusion and exclusion criteria
Inclusion criteria: satisfaction with participating in the study; age over 18 years old; serum albumin levels less than 3.2 g/l and at least 3 months of peritoneal dialysis has passed in cachexic person. Exclusion criteria: intolerance to syrup; kidney transplantation;, death.

Intervention groups
Syrup, manufactured by Barij Essance Co., Iran; dose is 5 ml three times a day, before each meal for at least two months. Patient monitoring during the study to ensure adherence to treatment.

Main outcome variables
Improvement of weight indices; cachexia and laboratory indices

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160713028901N3**
Registration date: **2020-10-20, 1399/07/29**
Registration timing: **prospective**

Last update: **2020-10-20, 1399/07/29**
Update count: **0**

Registration date
2020-10-20, 1399/07/29

Registrant information

Name
Shirinsadat Badri

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3792 7068

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badri@pharm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-05, 1399/08/15

Expected recruitment end date
2021-09-06, 1400/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of herbal extracts (Punica Granatum) on weight and cachexia indices in peritoneal dialysis patients

Public title
Effect of herbal extracts on weight and cachexia indices in peritoneal dialysis patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction with participation in the study Age over 18 years old Albumin levels less than 3.2 g/l At least 3 months have passed since peritoneal dialysis and they have now been diagnosed with cachexia

Exclusion criteria:

Syrup intolerance Kidney transplantation Death

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization: Blocks of 4 will be used and patients will be assigned to drug and control groups based on the determined sequences in the blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, Isfahan University of Medical Sciences

Street address

Hezar-Jerib street

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Isfehan

Postal code

8174673461

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.MUI.MED.REC.1399.431

Health conditions studied

1

Description of health condition studied

Peritoneal dialysis

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Weight indices

Timepoint

Before the start and at the end of first month and second month

Method of measurement

Body analyzer device and Strip meter

2

Description

Cachexia

Timepoint

Before the start and at the end of first month and second month

Method of measurement

Visual Analog Scale questionnaire

3

Description

Serum albumin

Timepoint

Before the start and at the end of second month

Method of measurement

Elisa

4

Description

Serum triglyceride

Timepoint

Before the start and at the end of second month

Method of measurement

Elisa

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: consuming herbal extracts (Punica Granatum)Syrup, manufactured by Barij Essance Co., Iran; dose is 5 ml three times a day, before each meal for at least two months. Patient monitoring during the study to ensure adherence to treatment.

Category
Treatment - Drugs

2

Description
Control group: Peritoneal dialysis patients that received neither intervention drug nor placebo drug
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Full name of responsible person
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Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
confidentiality of information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available