

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7068

###### Email address

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

##### **City**

Isfahan

##### **Province**

Isfahan

##### **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**

Shirinsadat Badri

**Street address**

Sofe Blvd

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

alzahra@mui.ac.ir

**Web page address**<http://alzahra.mui.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Shaghayegh Haghjoi Javanmard

**Street address**

Vice Chancellery of Research, Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

research@mui.ac.ir

**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**

Shirinsadat Badri

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Sofe Ave. Isfahan Kidney Diseases Research Center, Isfahan, Iran.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7068

**Email**

badri@pharm.mui.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shirinsadat Badri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Hezar Jarib, Isfahan, Iran.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

0098 3792 7068

**Email**

badri@pharm.mui.ac.ir

**Postal code**

8174673461

**Phone**

+98 31 3792 7069

**Email**

badri@pharm.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shirinsadat Badri

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Hezar jarib street, Isfahan, iran.

**City**

Isfahan

**Province**

Isfahan

## 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