

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the effect of Pomegranate extract on nutritional status, anemia and inflammatory biomarkers of hemodialysis patients

#### Protocol summary

##### Summary

This clinical trial has been designated to study the probable effects of pomegranate extract on inflammatory biomarkers of hemodialysis patients such as CRP, IL-6 and also on two clinical outcomes, nutritional status and anemia. Inclusion criterion comprises receiving hemodialysis therapy for three consecutive months. Exclusion criteria are history of hypersensitivity to pomegranate; kidney transplant less than 6 months before study enrollment; vitamin E (60 IU/day or more), vitamin C (500 mg/day or more), or other antioxidant supplements during the month before the study; history of hospitalization during 3 months before the study; patients with life-threatening comorbidities including malignancies and being severely deconditioned. In this study 80 hemodialysis patients aging above 18 will be randomly allocated to receive pomegranate extract or placebo for 8 weeks. Changes in primary outcome variables including CRP, leptin, Interleukin-6, hemoglobin (in patients' blood samples) and nutritional status (through MIS) will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201502225161N2**

Registration date: **2016-06-23, 1395/04/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-23, 1395/04/03

##### Registrant information

##### Name

Vahideh Yavari

##### Name of organization / entity

Shiraz University of Medical Sciences, Shiraz, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1646 7125

##### Email address

yavariv@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-Chancellery for Research and Technology Affairs, Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-08-06, 1394/05/15

##### Expected recruitment end date

2015-09-06, 1394/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of Pomegranate extract on nutritional status, anemia and inflammatory biomarkers of hemodialysis patients

##### Public title

Pomegranate extract and hemodialysis patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: ESRD patients on chronic hemodialysis for at least three consecutive months Exclusion criteria: history of hypersensitivity to pomegranate; kidney transplant less than 6 months before study enrollment; vitamin E (60 IU/day or more), vitamin C (500 mg/day or more), or other antioxidant supplements during the

month before the study; history of hospitalization during 3 months before the study; patients with life-threatening comorbidities including malignancies; being severely deconditioned

#### **Age**

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

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Medical Research Ethics Committee

###### **Street address**

Medical Research Ethics Committee, Vice-Chancellery for Research and Technology Affairs, Shiraz University of Medical Sciences

###### **City**

Shiraz

###### **Postal code**

###### **Approval date**

2015-05-17, 1394/02/27

###### **Ethics committee reference number**

ir.sums.rec.1394.31

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

End Stage Renal Disease

##### **ICD-10 code**

N18.5

##### **ICD-10 code description**

Chronic kidney disease, stage 5

### **Primary outcomes**

#### **1**

##### **Description**

CRP

##### **Timepoint**

before and after the intervention

##### **Method of measurement**

blood sample

#### **2**

##### **Description**

Hemoglobin

##### **Timepoint**

before and after the intervention

##### **Method of measurement**

blood sample

#### **3**

##### **Description**

Leptin

##### **Timepoint**

before and after the intervention

##### **Method of measurement**

blood sample

#### **4**

##### **Description**

Nutritional status

##### **Timepoint**

before and after the intervention

##### **Method of measurement**

MIS

#### **5**

##### **Description**

IL-6

##### **Timepoint**

before and after the intervention

##### **Method of measurement**

blood sample

### **Secondary outcomes**

#### **1**

##### **Description**

Adverse drug reactions

##### **Timepoint**

during intervention

##### **Method of measurement**

patient-based reports

### **Intervention groups**

## 1

### Description

Intervention group: 2 g of Pomegranate extract before every dialysis session for 8 weeks

### Category

Treatment - Drugs

## 2

### Description

control group: 4 capsules of placebo before every hemodialysis session

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hemodialysis Unit, Namazi Hospital

##### Full name of responsible person

Dr. Mansooreh Faghihi

##### Street address

Namazi Hospital, Namazi Square

##### City

Shiraz

### 2

#### Recruitment center

##### Name of recruitment center

Hemodialysis Unit, Shahid Faghihi Hospital

##### Full name of responsible person

Dr. Ramin Radmehr

##### Street address

Shahid Faghihi Hospital, Zand BLVD

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-Chancellor for Research and Technology Affairs

##### Full name of responsible person

Dr. Seyed Basir Hashemi

##### Street address

Central Building of Shiraz University of Medical Sciences, 7th floor, Zand BLVD

##### City

Shiraz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice-Chancellor for Research and Technology Affairs

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences, Nephrology Department

#### Full name of responsible person

Dr Jamshid Roozbeh

#### Position

Nephrologist/ Full professor

#### Other areas of specialty/work

#### Street address

Namazi hospital, Nephrology Department Office

#### City

Shiraz

#### Postal code

#### Phone

+98 71 3647 4316

#### Fax

#### Email

roozbehj@hotmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences, Nephrology Department

#### Full name of responsible person

Dr Vahideh Yavari

#### Position

Nephrology Fellow

#### Other areas of specialty/work

#### Street address

Namazi hospital, Nephrology Department Office

#### City

Shiraz

#### Postal code

#### Phone

+98 71 3647 4316

#### Fax

#### Email

yavariv@gmail.com

#### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences, Nephrology  
Department

**Full name of responsible person**

Dr. Vahideh Yavari

**Position**

Nephrology Fellow

**Other areas of specialty/work****Street address****City****Postal code****Phone**

00

**Fax****Email**

yavariv@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*