Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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

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Name of organization / entity

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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
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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
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Person responsible for updating data

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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