Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of pomegranate juice on blood pressure, lipids profile, inflammatory and oxidative stress biomarkers in hemodialysis patients

Protocol summary

Summary

Objective: To determine the effects of pomegranate juice consumption on blood pressure , lipid profile , inflammatory markers and oxidative stress in patients undergoing hemodialysis Study design : Crossover clinical trial Study population: Hemodialysis Patients Inclusion criteria : patients undergoing hemodialysis treatment for more than 3 months , patients with ESRD undergoing hemodialysis three times a week for at least 90 days ; age 18 to 65 years, life expectancy greater than one year ; potassium level less than 5 mEq / L ;Let your doctor , informed consent to participate in the study Non- inclusion criteria : cancer activist , has a digestive disorder that requires nutritional support preparations ; poor adherence to hemodialysis or drugs ;Kidney transplant less than 6 months ; taking antioxidant supplements such as vitamins E and C during one month prior to the study , the use of Vnvfr at least two weeks before the start of the study , patients hospitalized for more than 5 days in a month before registration; a history of thrombosis,Coronary artery bypass surgery and stroke in patients with acute infections or inflammatory disease ; patients who are pregnant or who plan to become pregnant during the study period . Exclusion criteria : lack of pomegranate juice consumption by more than 3 days a month ; change the pressure medications and cholesterol ; non-compliance with dietary recommendations , hospitalization for more than 5 days in a month ; the loss of the conditions of entry to study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070428797N1**
Registration date: **2016-07-24, 1395/05/03**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-07-24, 1395/05/03

Registrant information

Name
Reza Barati Boldaji
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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+98 38 3464 2735
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Recruitment status

Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-04-29, 1395/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pomegranate juice on blood pressure, lipids profile, inflammatory and oxidative stress biomarkers in hemodialysis patients

Public title

The effect of pomegranate juice on patients undergoing hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients undergoing hemodialysis treatment for more than 3 months , patients with ESRD undergoing hemodialysis three times a week for at least 90 days ; age 18 to 65 years, life expectancy greater than one year ; potassium level less than 5 mEq / L ;Let your doctor , informed consent to participate in the study Non- inclusion criteria : AIDS, cancer activist , has a digestive disorder that requires nutritional support preparations ; poor adherence to hemodialysis or drugs ;Kidney transplant less than 6 months ; taking antioxidant supplements such as vitamins E and C during one month prior to the study , the use of Vnvfr at least two weeks before the start of the study , patients hospitalized for more than 5 days in a month before registration; a history of thrombosis,Coronary artery bypass surgery and stroke in patients with acute infections or inflammatory disease ; patients who are pregnant or who plan to become pregnant during the study period . Exclusion criteria : lack of pomegranate juice consumption by more than 3 days a month ; change the pressure medications and cholesterol ; non-compliance with dietary recommendations , hospitalization for more than 5 days in a month ; the loss of the conditions of entry to study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz Zand Ave.

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.SUMS.REC.1394.210

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Baseline - 2 months , 3 months and 5 months after the start of the study

Method of measurement

Mercury manometers

2

Description

Diastolic blood pressure

Timepoint

Baseline - 2 months , 3 months and 5 months after the start of the study

Method of measurement

Mercury manometers

3

Description

TC

Timepoint

Baseline - 2 months , 3 months and 5 months after the start of the study

Method of measurement

kit

4

Description

LDL-C

Timepoint

Baseline - 2 months , 3 months and 5 months after the start of the study

Method of measurement

kit

5

Description
HDL-C
Timepoint
Baseline - 2 months , 3 months and 5 months after the start of the study
Method of measurement
kit

6

Description
TG
Timepoint
Baseline - 2 months , 3 months and 5 months after the start of the study
Method of measurement
kit

7

Description
Total Antioxidant capacity
Timepoint
Baseline - 2 months , 3 months and 5 months after the start of the study
Method of measurement
kit

8

Description
Malondialdehyde
Timepoint
Baseline - 2 months , 3 months and 5 months after the start of the study
Method of measurement
kit

9

Description
IL- 6
Timepoint
Baseline - 2 months , 3 months and 5 months after the start of the study
Method of measurement
kit

10

Description
Anthropometric indices
Timepoint
Baseline - 2 months , 3 months and 5 months after the start of the study
Method of measurement
Weighing scale,Tape measure,BIA

Secondary outcomes

1

Description
potassium
Timepoint
Baseline - 2 months , 3 months and 5 months after the start of the study
Method of measurement
blood test

Intervention groups

1

Description
In the first two months Group A: One hundred ml of pomegranate juice ; immediately after each dialysis session , three times a week for two months Group B: usual care in hemodialysis patients
Category
Treatment - Other

2

Description
In the second Group B: One hundred ml of pomegranate juice ; immediately after each dialysis session , three times a week for two months Group A: usual care in hemodialysis patients
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Reza Barati
Street address
City
Shiraz

2

Recruitment center
Name of recruitment center
Faghihi Hospital
Full name of responsible person
Reza Barati
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Akhlaghi

Street address

Boulevard Razi School of Nutrition and Food Science

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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

School of Nutrition and Food Sciences

Full name of responsible person

Reza Barati

Position

Masters student

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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