Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of Vitamin C on Oxidative Stress in Patients Undergoing Continuous Ambulatory Peritoneal Dialysis

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is effect of vitamin C on oxidative stress in patients undergoing continuous ambulatory peritoneal dialysis. Total of sample size is 40 patient with ages: 18-65 years old. The patients With peritonitis or any other infection at least four weeks before sampling, using non-steroidal and allopurinol drugs, using antioxidant drugs will be excluded. Nurse drug distributor and patients do not know about the protocol of the study and type of drug. Initially, all patients are undergoing washout for 8 weeks, it means all patients do not consume antioxidants that have already used. The patients are randomly divided into two groups by blocked randomization. After washout, First group receives 250 miligram of vitamin c and 250 miligram of vitamin B6 once in one day for 8 weeks. The second group as a control group receives placebo capsule once in one day for 8 weeks. Patients basic information such as age and sex, stature, BMI, serum triglyceride, low density lipoprotein, high density lipoprotein, total cholesterol, fasting blood sugar, hemoglobin A1c (HbA1c), albumin, uric acid, C-reactive protein, total antioxidants capacity, malonyl dialdehyde will be recorded in both groups before intervention (after washout) and after the intervention period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050227675N2**
Registration date: **2017-01-20, 1395/11/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-12-25, 1395/10/05

Expected recruitment end date

2017-04-25, 1396/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin C on Oxidative Stress in Patients Undergoing Continuous Ambulatory Peritoneal Dialysis

Public title

Effect of Vitamin C on Stress in Peritoneal Dialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients treated with peritoneal

dialysis for more than six months; Patients with ages: 18-65 years old; Having a regular program of CAPD, three to four times swap by two liters isotonic or hypertonic glucose solution or icodextrin solution for at least 3 months. Exclusion Criteria: The patients With peritonitis or any other infection at least four weeks before sampling; The incidence of any chronic inflammatory disease; using non-steroidal and allopurinol and antioxidant drugs; Inadequate control of diabetes or HbA1c more than 7.5 %.

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
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address
Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City
Ahvaz

Postal code

Approval date
2016-12-24, 1395/10/04

Ethics committee reference number
IR.AJUMS.REC.1395.583

Health conditions studied

1

Description of health condition studied
Peritoneal dialysis patients

ICD-10 code
N18.0

ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
Peritoneum and serum total antioxidants capacity (TAC)

Timepoint
Before intervention and after completion of intervention in the eighth week

Method of measurement
Venous and peritoneal sampling and sent to the laboratory

2

Description
Malonyl dialdehyde (MDA)

Timepoint
Before intervention and after completion of intervention in the eighth week

Method of measurement
Venous and peritoneal sampling and sent to the laboratory

Secondary outcomes

1

Description
uric acid

Timepoint
Before intervention and after completion of intervention in the eighth week

Method of measurement
Venous sampling and sent to the laboratory

2

Description
Albumin

Timepoint
Before intervention and after completion of intervention in the eighth week

Method of measurement
Venous sampling and sent to the laboratory

3

Description
C-reactive protein (CRP)

Timepoint
Before intervention and after completion of intervention in the eighth week

Method of measurement
Venous sampling and sent to the laboratory

4

Description
hemoglobin A1c (HbA1c)
Timepoint
Before intervention and after completion of intervention in the eighth week
Method of measurement
Venous sampling and sent to the laboratory

5

Description
Low density lipoprotein (LDL) and high density lipoprotein (HDL)
Timepoint
Before intervention and after completion of intervention in the eighth week
Method of measurement
Venous sampling and sent to the laboratory

6

Description
Fasting blood sugar
Timepoint
Before intervention and after completion of intervention in the eighth week
Method of measurement
Venous sampling and sent to the laboratory

7

Description
serum triglyceride
Timepoint
Before intervention and after completion of intervention in the eighth week
Method of measurement
Venous sampling and sent to the laboratory

Intervention groups

1

Description
Group I (intervention group): Prescription 250 miligram of vitamin c and 250 miligram of vitamin B6 once in one day for 8 weeks
Category
Treatment - Drugs

2

Description
Group II (control group): Prescription 250 mg of placebo capsule, once in one day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Heshmat allah Shahbazian
Street address
Khomeini Hospital, ShahidAhwazian St., Ahwaz
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Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Nader Saki
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City
Ahvaz
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 Of Ahvaz Jundishapur 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
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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