

# 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 milligram of vitamin c and 250 milligram 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

###### Name

Farshid Padyab

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3222 2922

###### Email address

padyab.f@ajums.ac.ir

##### 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 milligram of vitamin c and 250 milligram 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

**City**

Ahwaz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor For Research Of Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Nader Saki

**Street address**

Vice chancellor For Research Of Ahwaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahwaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahwaz

**City**

Ahwaz

**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 Ahwaz 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**

Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Farshid Padyab

**Position**

Resident in internal medicine

**Other areas of specialty/work**

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