

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Evaluation of the effect of vitamin C supplementation on selected blood laboratory indicators of chronic kidney diseases, a double blind randomized control trial

Protocol summary

Study aim

Determining the effect of vitamin C supplementation on selected blood laboratory indicators of chronic kidney patients

Design

This is a parallel randomized controlled clinical trial that will be performed on 106 patients with Chronic renal failure. Randomization in this research is done using quadri blocks using syntax written in SPSS program.

Settings and conduct

This study will conduct as a clinical trial study with 106 patients who will refer to Imam Hossain Hospital of Shahroud. Patients must sign an informed consent form before entering the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with definitive diagnosis of chronic kidney disease and need dialysis; Age range 15-65 years; History of dialysis for at least six consecutive months; Stable vital signs; Have a controlled and consistent diet throughout the study; Conscious consent to participate in research. Exclusion criteria: Existence of digestive problems such as severe nausea and vomiting; Existence of severe and relatively severe coagulation problems; Existence of chronic heart and liver disease at the same time; Take any vitamin C supplements in the past month; Any changes in diet without notice during the study; Withdrawal or regret of conducting research at any stage of research.

Intervention groups

For patients in the intervention group, after justifying the patients and providing the necessary training, routine treatment (including: hemodialysis, medication and diet) + 250 mg of vitamin C tablets once a day during the study (12 weeks) is prescribed. For patients in the control group, after justifying the patients and providing the necessary training, only routine treatment (including: hemodialysis, medication and diet) is prescribed during

the study (12 weeks).

Main outcome variables

Measurement of serum potassium; Measurement of serum calcium and Blood sugar measurement.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N25**

Registration date: **2022-01-31, 1400/11/11**

Registration timing: **prospective**

Last update: **2022-01-31, 1400/11/11**

Update count: **0**

Registration date

2022-01-31, 1400/11/11

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Ssciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin C supplementation on selected blood laboratory indicators of chronic kidney diseases, a double blind randomized control trial

Public title

Evaluation of the effect of vitamin C on some blood indicators of dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with definitive diagnosis of chronic kidney disease and need dialysis; Age range 15-65 years; History of dialysis for at least six consecutive months; Stable vital signs; Have a controlled and consistent diet throughout the study; Conscious consent to participate in research.

Exclusion criteria:

Existence of digestive problems such as severe nausea and vomiting; Existence of severe and relatively severe coagulation problems; Existence of chronic heart and liver disease at the same time; Take any vitamin C supplements in the past month; Any changes in diet without notice during the study; Withdrawal or regret of conducting research at any stage of research.

AgeFrom **15 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **106****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients were allocated to intervention and control groups according to random allocation table that illustrated by a statistician. Randomization was done using permuted block randomization method (Block size was 4) using blocked random allocation syntax in SPSS software. For calculation sample size was 106 and number of blocks was 27. Allocation concealment was done using closed opaque envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients; clinical caregiver, outcome evaluator and analyzer it are blinded. The division of

patients into two groups intervention and control, review and record test results is done by a qualified nurse who has no knowledge of the actions performed in the two groups. Data analysis will also be performed by a project epidemiologist who has no knowledge of patient grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

City

Shahroud

Province

Semnan

Postal code

3616647555

Approval date

2022-01-05, 1400/10/15

Ethics committee reference number

IR.SHMU.REC.1400.236

Health conditions studied**1****Description of health condition studied**

Chronic kidney disease

ICD-10 code

N18.4

ICD-10 code description

Chronic kidney disease, stage 4 (severe)

Primary outcomes**1****Description**

Measurement of serum potassium

Timepoint

Once a month

Method of measurement

Standard laboratory method

2**Description**

Measurement of serum calcium
Timepoint
Once a month
Method of measurement
Standard laboratory method

3

Description
Blood sugar measurement
Timepoint
Once a month
Method of measurement
Standard laboratory method

4

Description
Measurement of hemoglobin
Timepoint
Once a month
Method of measurement
Standard laboratory method

Secondary outcomes

1

Description
Dialysis adequacy measurement
Timepoint
Once a month
Method of measurement
Dialysis adequacy indicators KT/V

Intervention groups

1

Description
Intervention group: for patients in the intervention group, after justifying the patients and providing the necessary training, routine treatment (including: hemodialysis, medication and diet) + 250 mg of vitamin C tablets once a day during the study (12 weeks) is prescribed.
Category
Treatment - Drugs

2

Description
Control group: for patients in the control group, after justifying the patients and providing the necessary training, only routine treatment (including: hemodialysis, medication and diet) is prescribed during the study (12 weeks).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital of Shahroud
Full name of responsible person
Dr. Hoofar Rafiei
Street address
Imam Hossein Hospital., End Imam street., Shahroud , Iran
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
rafiei@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hasan Imamian
Street address
Vice chancellor for research; Shahroud University medical Sciences ,7th Tir squar, Shahroud
City
Shahroud
Province
Semnan
Postal code
3616647555
Phone
+98 23 3239 4499
Fax
+98 23 3239 4800
Email
pajouhesh@shmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research; Shahroud University medical and Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mehdi Feyzabadi

Position

Internal resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Imam Hossein hospital., End Imam street., Shahroud., Iran

City

Shahroud

Province

Semnan

Postal code

3616611151

Phone

+98 23 3234 2000

Fax

+98 23 3233 3902

Email

mehdifeyzabadi082@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hoofar Rafiei

Position

Nephrologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

آدرس خیابان Imam Hossein hospital., End Imam street., Shahroud., Iran

City

Shahroud

Province

Semnan

Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
rafiei@shmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr.Mohammad Bagher Sohrabi

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Imam Hossein Hospital., End Imam street., Shahroud., Iran

City

Shahroud

Province

Semnan

Postal code

3616611151

Phone

+98 23 3234 2000

Fax

+98 23 3233 3902

Email

mb.sohrabi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available