Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Intravenous Vitamin C Supplementation on the Quality of Sleep, Itching,Restlessleg Syndrome in Patients Undergoing Hemodialysis In Tohid Hospital in Sanandaj at 2016

Protocol summary

Study aim

The purpose of this study was to determine the effect of intravenous vitamin C on sleep quality, Itching and Restless leg Syndrome in hemodialysis patients.

Design

Double-blind clinical trial with two parallel arm

Settings and conduct

This study was performed on chronic renal failure patients undergoing dialysis in Sanandaj Tohid Hospital in double blinded two arm design, by using the same method of packaging and drug delivery and package coding. Patients arriving after Signed Consent Consciously, an envelope will be selected from the envelope containing the code, and the will receive the medicine by same code .

Participants/Inclusion and exclusion criteria

inclusion: Patients with low sleep quality (score less than 5 based on global scores) Kidney failure, dialysis for at least 6 months, signing Informed consent, dialysis at least 3 times a week. Insomnia and or itching and or restless leg syndrome Exclusion : kidney transplantation and returned to hemodialysis. Dissatisfaction with the company in the study Failure to cooperate in completing the questionnaire People who have recived vitamins C, E, or fish oil during the two months before the study history of mental illness, severe heart and respiratory disease, or history of infectious disease three months before the study began. Taking immunosuppressive drugs in the last two months.

Intervention groups

intervention group received a 5-cc (500 milligram) vial of vitamin C from the Daropakhsh company control group, 5 cc normal saline was given as a placebo for injection three times a week at the end of each dialysis session and intravenously for eight weeks.

Main outcome variables

Itching, sleep Quality, Restless leg syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141208020249N4**
Registration date: **2018-12-05, 1397/09/14**
Registration timing: **retrospective**

Last update: **2018-12-05, 1397/09/14**
Update count: **0**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

Behzad Khalafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 45 3344 9697

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-04-02, 1394/01/13

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

2015-04-19, 1394/01/30

Actual recruitment end date

2016-07-20, 1395/04/30

Trial completion date

2016-09-20, 1395/06/30

Scientific title
Effect of Intravenous Vitamin C Supplementation on the Quality of Sleep, Itching,Restlessleg Syndrome in Patients Undergoing Hemodialysis In Tohid Hospital in Sanandaj at 2016

Public title
Intravenous Vitamin C Supplementation on the Quality of Sleep, Itching,Restlessleg Syndrome in Patients Undergoing Hemodialysis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with low sleep quality (score less than 5 based on global scores) Kidney failure, which has been dialyzed for at least 6 months signing Informed consent Kidney failure, which is dialyzed at least 3 times a week. Insomnia and or itching and or restless leg syndrome 18 to 70 years old

Exclusion criteria:
Dissatisfaction with the company in the study Failure to cooperate in completing the Petersburg quality of sleep questionnaire People who have recived vitamins C, E, or multi-vitamins containing vitamin C, E or fish oil during the two months before the study A history of mental illness, severe heart and respiratory disease, or a history of infectious disease three months before the study began. Taking immunosuppressive drugs in the last two months. Patients who have undergone kidney transplantation and returned to hemodialysis.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Prior to the commencement of the study, the code of medication prepared pre-prepared by a pharmacist outside the study is placed in the envelope, and the patient chooses to choose one of the envelopes upon signing the consent after signing consent. The medication code will not be delivered to the executive team until the completion of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs and placebo are packaged and coded by a pharmacist outside the study in similar containers and in similar sizes. The drug code is not provided to the researcher until the end of the study and the start of the analyzes. The patient researcher and clinical evaluator were also blinded of the contents of the drug containers.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
pasdaran Blvd, opposite Shadi Hotel, Kurdistan University of Medical Sciences, Sanandaj, Management of Medical Researches and Information. POB 6617713446

City
sanandaj

Province
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Postal code
6617713446

Approval date
2016-04-08, 1395/01/20

Ethics committee reference number
IR.MUK.REC.1395.14

Health conditions studied

1

Description of health condition studied
Chronic kidney disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

2

Description of health condition studied
restless leg syndrome

ICD-10 code
G25.81

ICD-10 code description
Restless legs syndrome

3

Description of health condition studied
Sleep Quality

ICD-10 code

G47.00

ICD-10 code description

Insomnia, unspecified

Primary outcomes

1

Description

itching

Timepoint

At the start of the study and after 8 weeks receiving the drug

Method of measurement

Level of itching according to VAS criteria

2

Description

restless leg syndrome

Timepoint

At the start of the study and after 8 weeks receiving the drug

Method of measurement

history taking and Clinical Evaluation

3

Description

Sleep Quality

Timepoint

At the start of the study and after 8 weeks receiving the drug

Method of measurement

Pittsburgh Sleep Quality Standards Questionnaire (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People who need dialysis which referring to dialysis department of Sanandaj Tohid Medical CenterThe intervention group received a 5-cc (500 milligram) vial of vitamin C from the Daropakhsh company

Category

Rehabilitation

2

Description

Control group: People who need dialysis which referring to dialysis department of Sanandaj Tohid Medical Center. In the control group, 5 cc normal saline was given as a placebo for injection three times a week at the end of each dialysis session and intravenously for eight weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Shahdak Dadashpour

Street address

Gheriashan St, Tohid Hospital, Department of Internal Medicine

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+98 87 3366 4645

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shahdakdadashpour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

Street address

Sanandaj, Kurdistan University of Medical Sciences, opposite Shadi Hotel, Kurdistan University of Medical Science, POB 6617713446 Management of medical research and information

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ebrahimghaderi@yahoo.com

Grant name

Grant code / Reference number

1395.14

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

Yes

Title of funding source

Sanandaj University of Medical 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

Sanandaj University of Medical Sciences

Full name of responsible person

Minoo sadat Hajmiri

Position

Internalist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Shadak Dadashpour

Position

Adult Nephrologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Research Associate / Researcher Soldier - General Physician of Kurdistan University of Medical Scien

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Shahdak Dadashpour - Tohid Hospital - Kurdistan University of Medical Science

What processes are involved for a request to access data/document

After submitting a request to the Kurdistan Research and

Technology Dept. of Science and Technology, a call for submission is given.

Comments