

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of Vitamin C and Ferrous Sulfate with Ferrous Sulfate along on Restless leg of hemodialysis patients, a double blind randomized control trial

Protocol summary

Study aim

Determine the effect of vitamin C plus iron in the treatment of Restless leg syndrome of hemodialysis patients

Design

This double blind clinical trial is performed on 80 patients with Restless leg syndrome that randomly divided into two equal groups in parallel. Block randomization method will be used for random allocation. The blocks size will be 4 and for this purpose; 20 blocks with 4 subjects in each block will be used. For selecting each blocks; dice dropped and the block number will be selected. This procedure continued to completed the allocation and reached to sample size.

Settings and conduct

This study was conducted as a clinical trial study with 80 patients who referred to hemodialysis ward of Imam Hossain Hospital of Shahroud. Patients must sign an informed consent form before entering the study. In this study; patients, clinical caregiver and the analyzer was blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged over 15 and under 70 years; definitive diagnosis of restless leg syndrome; the absence of underlying disorders of the skeletal system and the satisfaction in the research. Exclusion criteria: Patient's unstable hemodynamics; the need to kidney transplantation before the completion of the study; the presence of abnormalities in the skeletal system and the dissatisfaction in the research.

Intervention groups

Patients entered into the study are divided into intervention and control groups. In the intervention group; treatment with vitamin C plus ferrous sulfate will be prescribed in the third month. In the control group; treatment with just ferrous sulfate tablet in the third month will be performed.

Main outcome variables

Reduced severity of Restless leg syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N15**

Registration date: **2019-04-25, 1398/02/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-25, 1398/02/05**

Update count: **0**

Registration date

2019-04-25, 1398/02/05

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of university

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of Vitamin C and Ferrous Sulfate with Ferrous Sulfate along on Restless leg of hemodialysis patients, a double blind randomized control trial

Public title
Evaluation effects of Vitamin C and Ferrous Sulfate in Restless leg treatment of hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients under regular hemodialysis Age over 15 and under 70 years of patients Definitive diagnosis of restless leg syndrome No specific medication associated with restless leg therapy in the last two weeks The absence of underlying disorders of the skeletal system Having of satisfaction in research
Exclusion criteria:
Need to kidney transplant before study completion Hyperparathyroidism The presence of any underlying abnormalities of the skeletal system Unstable of vital signs and hemodynamic Dissatisfaction in research

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: use block. Random unit: individual. Randomization tool: statistical software. Sequence building: using randomized 4 in 4 blocks. Hiding method: use envelopes in the package.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients; clinical caregiver and analyzer it are blinded. The division of patients into two groups A and B is done by a qualified nurse who has no knowledge of the actions performed in the two groups. Do clinical examination of patients and results recorder will be done by a qualified nurse without any knowledge of the type of intervention and patients.

Placebo
Not used

Assignment
Parallel

Other design features
Patients entered into the study are divided into two groups of intervention and control. Patients in the intervention group; in addition to get the iron pill, will also receive vitamin C tablets. Patients in the control group will be only receive iron tablets.

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
2019-03-11, 1397/12/20

Ethics committee reference number
IR.SHMU.REC.1397.223

Health conditions studied

1

Description of health condition studied
Restless legs syndrome

ICD-10 code
G25.8

ICD-10 code description
Other specified extrapyramidal and movement disorders

Primary outcomes

1

Description
Severity of Restless Leg Syndroum

Timepoint
Once a Month

Method of measurement
Standard Questioner of Restless Leg syndrome evaluation

Secondary outcomes
empty

Intervention groups

1

Description

In the intervention group; treatment with vitamin C tablets plus ferrous sulfate tablets with initial dose of vitamin C (250 mg) plus a ferrous sulfate (60 mg) daily in the first month; two tablets of vitamin C (500 mg) plus two Ferrous sulfate tablets (120 mg) in the second month and 3 tablets of vitamin C (750 mg) plus three tablets of Ferrous sulfate (180 mg) in the third month will be prescribed.

Category

Treatment - Drugs

2

Description

Control group: In the control group; treatment will be done only one Ferrous sulfate tablet (60 mg) in the first month; two tablets of Ferrous sulfate (120 mg) in the second month and three tablets of Ferrous sulfate (180 mg) in the third month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Shahroud

Full name of responsible person

Dr.Monireh Amerian

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research; Shahroud University medical and Sciences

Full name of responsible person

Dr. Mohammad Hasan Imamian

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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; Shahroud University medical and Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

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

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Person responsible for scientific inquiries

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Dr.Monireh Amerian

Position

Nephrologist

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Subspecialist

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Latest degree

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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