Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of treatment with vitamin E compared with relaxation in the treatment of restless legs syndrome (RLS) in HD patients in Shahroud Imam Hussain Hospital

Protocol summary

Summary

The purpose of the study: efficacy of treatment with vitamin E compared with relaxation in the treatment of restless legs syndrome (RLS) in HD patients in Shahroud Imam Hussain Hospital. Design study: randomized, double blind, without placebo control, single-center, phase 3 trial. The study population: hemodialysis patients admitted in hemodialysis ward Inclusion criteria: people with chronic kidney disease on hemodialysis for more than 6 months; RLS diagnosis; no previous history or RLS or genetic RLS; not taking anticonvulsion medications, opioids or dopamine agonists. Exclusion criteria: previous history or genetic; Patients with RLS treatment of other drugs (such as dopamine agonists, anticonvulsants and opioids); Patients with mild RLS that there is a possibility of non-cooperation. Sample size: 90. Behavioral intervention: for 3 months during the intervention group counseling sessions for relaxation and yoga therapy training by a psychologist and a psychiatrist monitored for 15-minute sessions once a week for each patient is done And at the end of the questionnaire is to evaluate the changes in symptoms. Intervention time: before and 3 months after intervention Primary outcomes: the remission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082129463N1**
Registration date: **2016-09-14, 1395/06/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-14, 1395/06/24

Registrant information

Name

Hamraz Sadeghi

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences

Expected recruitment start date

2016-08-31, 1395/06/10

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of treatment with vitamin E compared with relaxation in the treatment of restless legs syndrome (RLS) in HD patients in Shahroud Imam Hussain Hospital

Public title

The effect of treatment with vitamin E compared with relaxation in the treatment of restless legs syndrome (RLS) in HD patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: people with chronic kidney disease on hemodialysis for more than 6 months; RLS diagnosis; no previous history or RLS or genetic RLS; not taking anticonvulsion medications, opioids or dopamine agonists. Exclusion criteria: previous history or genetic; Patients with RLS treatment of other drugs (such as dopamine agonists, anticonvulsants and opioids); Patients with mild RLS that there is a possibility of non-cooperation.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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
School of Medicine, Central Building Shahroud University of Medical Sciences, Haft Tir Square, Shahrud

City
Shahroud

Postal code

Approval date
2015-01-21, 1393/11/01

Ethics committee reference number
930/30

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
The remission

Timepoint
Before and 3 months after intervention

Method of measurement
International RLS severity survey questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Behavioral intervention: For 3 months during the intervention group counseling sessions for relaxation and yoga therapy training By a psychologist and a psychiatrist monitored for 15-minute sessions once a week for each patient is done And at the end of the questionnaire is to evaluate the changes in symptoms.

Category
Behavior

2

Description
The control group treated with vitamin E for 3 months at a dose of 400 mg daily fall And to one of their family members is recommended that regular intake of medication by the patient monitor.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hoseyn Hospital

Full name of responsible person
Hamraz Sadeghi

Street address
Imam Hoseyn Hospital, The end of the 28-meter Ayatollah Tohidi, Imam street

City
Shahrud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
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School of Medicine, Central Building Shahroud University of Medical Sciences, Haft Tir Square, Shahrud

City
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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
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Hamraz Sadeghi

Position
General physician

Other areas of specialty/work

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Person responsible for scientific inquiries

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Nephrology specialist

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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