

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

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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

Hamraz Sadeghi

Street address

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

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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