

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Study the effect of treatment with L Carnitine on severity of uremic restless legs syndrome in dialysis patients

Protocol summary

Study aim

Study effect of treatment with L Carnitine on severity of uremic restless legs syndrome In dialysis patients

Design

This study is a double-blinded clinical trial with a parallel design and a control group. The study population will include all dialysis patients with restless legs syndrome referred to Imam Reza Hospital of Kermanshah. 82 eligible individuals will be selected conveniently. A random table is used for randomization and participants are assigned to two groups of intervention and control.

Settings and conduct

This study, which will be conducted in Imam Reza Hospital of Kermanshah, is a double-blinded one. The clinical caregiver and outcome assessor will be kept blinded to which group will receive the new drugs and which groups will receive the placebos.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Dialysis patients with restless legs syndrome; Patient informed consent
Exclusion criteria: Patients diagnosed with anxiety disorders; Patients with a diagnosis of sleep disorders

Intervention groups

The intervention group will be treated daily with 500 mg L-carnitine tablets every 12 hours for three months. The control group will receive a 500 mg daily placebo (in pill form) every 12 hours for 3 months.

Main outcome variables

Severity of Restless Legs Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N171**

Registration date: **2021-07-04, 1400/04/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-04, 1400/04/13**

Update count: **0**

Registration date

2021-07-04, 1400/04/13

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-21, 1400/02/31

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of treatment with L Carnitine on severity of uremic restless legs syndrome in dialysis patients

Public title

Effect of L Carnitine on severity of uremic restless legs syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Dialysis patients with restless legs syndrome Patient informed consent

Exclusion criteria:
Patients diagnosed with anxiety disorders Patients with a diagnosis of sleep disorders

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random method. 82 cards are selected and numbers from 1-82 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. Paired numbers are assigned to the intervention group and odd numbers to the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs can only be identified by the serial number on the container. The serials are with the main researcher and will remain confidential until the end of the study. The clinician will not be aware of assigning individuals to study groups. The person evaluating the patients will also not know about the assignment. In fact, clinicians and outcome assessors are unaware of who is receiving the new drug. Therefore, this study will be double-blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical

Sciences

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2021-04-27, 1400/02/07

Ethics committee reference number
IR.KUMS.REC.1400.088

Health conditions studied

1

Description of health condition studied
Restless leg syndrome

ICD-10 code
G25.81

ICD-10 code description
Restless legs syndrome

Primary outcomes

1

Description
Severity of Restless Legs Syndrome

Timepoint
Beginning of treatment, sixth week and end of treatment (three months later)

Method of measurement
Based on clinical observation, physician and patient opinion

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 500 mg of L-carnitine tablets (Behta) daily, every 12 hours for three months.

Category
Treatment - Drugs

2

Description
The control group will receive a 500 mg daily placebo (in pill form and Amin Pharmaceutical Company) every 12 hours for 3 months.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital, Parastar Boulevard

Full name of responsible person

Mahnaz Khosravi

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

mahnazkhosravi141167@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

rkhodarahmi@mbrc.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mahnaz Khosravi

Position

Resident of Neurology

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

mahnazkhosravi141167@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hadi Ghrebaghian

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

h_azar2001@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mahnaz Khosravi

Position

Resident of Neurology

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Email

mahnazkhosravi141167@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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