Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of l-carnitine supplement and placebo on sleep quality in hemodialysis patients.

Protocol summary

Summary

This is a randomized double blind placebo-controlled clinical trial to evaluate the effect of l-carnitine on sleep quality of 56 hemodialysis patients in Emam Khomeini hospital of Shirvan. Inclusion criteria: Signing informed consent, Being on hemodialysis three times a week for at least 6 months prior to the study, age over 18. Exclusion criteria: Refusal at any time to continue the study, History of l-carnitine , vit c and vit E consumption, History of transquilizers, hypnotics or sedatives consumption, History of severe neuropsychology, cardiac, respiratory, liver disease, History of renal transplantation. After approving of the study by sciences vice chancellor of Sabzevar University of Medical Sciences and completing of written consent form by all participants in the study, Patients will be divided randomly into two equal groups. Intervention group will receive 500mg l-carnitine orally twice a day for 12 weeks and control group will receive placebo for 12 weeks. Also, the patients is asked during the study period, not to have any changes in medications, diet and exercise. At the beginning and end of the study, the Pittsburgh sleep quality index (PSQI) questionnaire will be completed by the patients to measure quality and sleep patterns.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030516848N1**
Registration date: **2014-05-03, 1393/02/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-03, 1393/02/13

Registrant information

Name
Maryam Hatami
Name of organization / entity
Sabzevar University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2014-03-22, 1393/01/02

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of l-carnitine supplement and placebo on sleep quality in hemodialysis patients.

Public title

Effect of l-carnitine on sleep quality in hemodialysis patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Signing informed consent, Being on hemodialysis three times a week for at least 6 months prior to the study, age over 18. Exclusion criteria: Refusal at any time to continue the study, History of l-carnitine ,

vit c and vit E consumption, History of transquilizers, hypnotics or sedatives consumption, History of severe neuropsychology, cardiac, respiratory, liver disease, History of renal transplantation.

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sabzevar University of Medical Scinces

Street address
School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

City
Sabzevar

Postal code

Approval date
2014-01-27, 1392/11/07

Ethics committee reference number
92.24.medsab.Rec

Health conditions studied

1

Description of health condition studied
Hemodialysis

ICD-10 code
Z49.1

ICD-10 code description
Extracorporeal dialysis

Primary outcomes

1

Description
sleep quality

Timepoint
before intervention and three months later

Method of measurement
PSQI=Pittsburgh sleep quality index

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 500mg l-carnitine orally twice a day for 12 weeks.

Category
Treatment - Drugs

2

Description
The control group will receive tablet similar to l-carnitine as placebo orally twice a day for 12 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomeini Hospital

Full name of responsible person
Foziyeh

Street address

City
Shirvan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Moosa Reza Tadayonfar

Street address
School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

City
Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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

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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