Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

L-carnitine effects on anemia improvement in patients undergoing hemodialysis

Protocol summary

Study aim
The study of effect of L-carnitine supplementation on anemia in hemodialysis patients

Design
Clinical trials having a control group, community parallel study, double-blind, randomized groups

Settings and conduct
This study will be performed in dialysis unit of Tohid hospital in Sanandaj by 100 patients with chronic renal failure, divided into two groups of 50. Patients in both the intervention and control groups and the nurses who provide the drug and the placebo to the patients will not be aware of the type of drug, and a completely same form of the drug and the placebo will be delivered to the patients. Patients in the intervention group treated by L-carnitine with a dose of 1 gr per day and the control group without L-carnitine, they received placebo for 12 weeks. Mean serum hemoglobin, ferritin and iron will be measured before and three months after starting treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1. Patients with chronic renal failure who are undergoing hemodialysis 2. Age over 20 years 3. Previous at least one year of hemodialysis treatment Non-inclusion criteria: 1. Infectious, hepatic, and malignant diseases 2. Previous consumption of L-Carnitine supplement 3. Use of corticosteroids 4. Narcotic drugs, alcohol and cigarette consumption

Intervention groups
The intervention group will receive L-carnitine at a dose of 1 g per day for three months. The control group will receive the placebo.

Main outcome variables
Hemoglobin, Iron, Ferritin, and Total Iron Binding Capacity(TIBC)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180921041080N1**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **retrospective**

Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date
2018-11-30, 1397/09/09

Registrant information

Name
Avin Khorshidi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3328 6114

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a.khorshidi@muk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
2018-08-23, 1397/06/01

Actual recruitment end date
2018-10-06, 1397/07/14

Trial completion date
empty

Scientific title
L-carnitine effects on anemia improvement in patients undergoing hemodialysis

Public title
The effect of L-carnitine in the treatment of anemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing hemodialysis Having anemia Hemodialysis more than one year Age more than 20 years
Exclusion criteria:
Having infectious, hepatic, and cancer diseases Previous use of L-carnitine supplement Use of corticosteroids Narcotic drugs, alcohol, and cigarette consumption
Age
From **20 years** old to **74 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation method was used to assign participants in blocks of four. There are six probabilities for block size of four (six cards). A hundred participants were assigned randomly using the cards twenty-five times. AABB ABAB BBAA BAAB ABBA BABA The first choice was done using simple randomizing method and table of random numbers. Having selected the first card, other participants are selected according to the rounds. Cards labelled (A) referred to intervention group, and cards labelled (B) referred to control group. Therefore, fifty participants are assigned in each group (intervention and control). Sampling will continue until all the participants are assigned in the groups randomly.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients in both the intervention and control groups and the nurses who provide the drug and the drug to the patients will not be aware of the type of drug. The placebo was similar to the drug in terms of shape, color, size, weight and packaging
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciencess
Street address
Pasdaran Ave
City
Sanandaj
Province
Kurdistan
Postal code
1344666177
Approval date
2018-02-21, 1396/12/02
Ethics committee reference number
IR.MUK.REC.1396/332

Health conditions studied

1

Description of health condition studied
Chronic renal Disease
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Anemia
Timepoint
Mean serum hemoglobin, ferritin and iron levels are measured at the beginning and three months after the start of treatment.
Method of measurement
Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group will treated for 12 weeks with a single daily dose of L-carnitine tablets containing one gram of L-carnitine tartrate produced by the Karen Pharmaceutical Company. The tablet will be taken with a glass of water after meals.
Category
Treatment - Drugs

2

Description
Control group: The patients of the control group were treated by placebo, which resembles L.Carnitine tablets with a dose of 1 gram completely, made by Karen Pharmaceutical Company one daily after meal for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Dialysis, Ṣanandaj Tohid Hospital, Sanandaj
Full name of responsible person
Anvar Mohamadi Baneh
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Sponsors / Funding sources

1

Sponsor
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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
Kurdistan 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
Kurdistan University of Medical Sciences
Full name of responsible person
Anvar Mohamadi Baneh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Regarding the fact that the present study has been registered as a research project in the “Research Management System of Medical Sciences University of Kurdistan”, it is required to present and register the final report in the “National Health Research Results Database”. Therefore, the sharing process of this study will be done step by step accordingly. It is essential to mention than the results of this study will be published in terms of statistical data, tables and figures in the extracted paper.
When the data will become available and for how long
One year
To whom data/document is available
Everyone
Under which criteria data/document could be used
After publishing article
From where data/document is obtainable
Regarding the fact that presenting and registering the results of the study in a profile on “National Health Research Database” of Medical Sciences University of Kurdistan, and publishing the final paper and registering the researchers’ information in the mentioned database, it will be possible to contact the researchers through emailing and deputy of research and technology of the university.
What processes are involved for a request to access data/document
The researchers will be willing to respond emails requesting information, which is not considered confidential and private, about the patients being studied. This is also possible through contacting deputy of research and technology of the university.
Comments