Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effect of intravenous Carnitine on hemoglobin and hematocrit level in chronic renal disease patients who are under hemodialysis treatment

Protocol summary

Summary
The purpose of this study is to investigate the effect of intravenous Carnitine on anemia in chronic renal disease patients who are under hemodialysis treatment. A total of 29 patients who were under hemodialysis for at least one year and they hadn't other reasons for their anemia were enrolled. The patients were assigned into two groups using a balanced block randomization method. After each dialysis session (3 times a week for 3 months), the intervention group was received an injection of 1 grams of intravenous Carnitine while the placebo group received 1 grams of distilled water as placebo. The levels of hemoglobin and hematocrit were measured and compared in each group before and after the treatment.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201010044865N1**
Registration date: **2010-11-18, 1389/08/27**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2010-11-18, 1389/08/27

Registrant information
Name
Maryam Khodaverdi
Name of organization / entity
Zanjan University of Medical Science
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Recruitment status
Recruitment complete
Funding source
Zanjan University of Medical Sciences

Expected recruitment start date
2004-06-17, 1383/03/28
Expected recruitment end date
2004-09-18, 1383/06/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of intravenous Carnitine on hemoglobin and hematocrit level in chronic renal disease patients who are under hemodialysis treatment

Public title
Effect of intravenous Carnitine on anemia in hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Hb less than10mg/dl, patients who had dialysed at least for one year, ferritin more than or equal to 100, SI/TIBC more than 20%, normal LFT, PTH less than or equal to 150pg/ml, negative β-HCG in female patients Exclusion criteria: receiving carnitine in 2 months prior to the study, pregnancy (positive β-HCG), Liver disease, ferritin less than 100, SI/TIBC less than 20%, PTH more than 150pg/ml
Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **29**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Blvd., Zanjan

City

Zanjan

Postal code

4515613191

Approval date

2004-03-16, 1382/12/26

Ethics committee reference number

13821216

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic renal failure

2

Description of health condition studied

Anaemia

ICD-10 code

D63

ICD-10 code description

Anaemia in chronic diseases classified elsewhere

Primary outcomes

1

Description

Hb

Timepoint

Before and after the intervention

Method of measurement

cell counter

2

Description

Hct

Timepoint

Before and after the intervention

Method of measurement

cellcounter

Secondary outcomes

1

Description

ferritine

Timepoint

before intervention

Method of measurement

Selectra Autoanalyzer

2

Description

TIBC

Timepoint

befor intervention

Method of measurement

Autonalizer selectra

3

Description

Liver Function Test

Timepoint

before intervention

Method of measurement

Selectra Autoanalyzer

4

Description

Paratormon Hormone

Timepoint

before intervention

Method of measurement

Selectra Autoanalyzer

5

Description
Pregnancy test-BHCG
Timepoint
before intervention
Method of measurement
Statfax Eliza

6

Description
Serum iron
Timepoint
before intervention
Method of measurement
Selectra Autoanalyzer

Intervention groups

1

Description
Intervention: carnitine, 1 gr interavenous, 3 times a week (after each dialysis session) for 3 months (36 sessions)
Category
Treatment - Drugs

2

Description
Control: dirtillor water, 1 gr intravenous, (3 times a week (after each dialysis session), for 3 months (36 sessions)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr Hospital
Full name of responsible person
Maryam Khodaverdi
Street address
Vali-e-Asr Hospital, Vali-e-Asr Square, Zanjan, Iran
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Faranak Sharifi
Street address
Zanjan University of Medical Sciences, Azadi Boulevard, Zanjan, Iran
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
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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