Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of carnitine supplementation on visceral proteins in hemodialysis patients

Protocol summary

Summary

In 2009, there were approximately 25,000 patients with Iran (3), this number increased to about 8% annually (4). In approximately 52.7% of the patients were treated with hemodialysis (5) the annual increase of 15% (6). Despite adequate hemodialysis for renal disease and adequate protein intake, long-term dialysis patients who are malnourished are. Protein malnutrition - energy is common in hemodialysis patients (7, 8). Studies performed in various states of protein malnutrition - Energy in hemodialysis patients from 16% to 90% have been reported (10-7).through the reduction of acyl-CoA reduces cardiac arrhythmias and ischemia, which is caused by reduced apoptosis. Deficiency of carnitine in patients with ESRD who have long dialysis are the most commonly happens while carnitine in the body from lysine and methionine synthesis is to achieve a balance of daily substance the body needs carnitine Exogenous the meat and dairy sources of carnitine exogenous precursors are (34), but patients on hemodialysis limited amounts of foods containing carnitine and the material it receives as cofactors and precursors of carnitine (such as B6 and niacin and vitamin C and lysine and methionineIt is not, therefore, important to justify a clinical trial designed to study the effect of carnitine supplementation on visceral protein levels in patients undergoing hemodialysis is designed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042913160N1**
Registration date: **2013-07-16, 1392/04/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-07-16, 1392/04/25

Registrant information

Name
Shima Dehghan
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-08-05, 1392/05/14

Expected recruitment end date

2014-01-04, 1392/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of carnitine supplementation on visceral proteins in hemodialysis patients

Public title

Effect of l-carnitine on malnutrition in hemodialysis patients

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria: patients on hemodialysis in last year,

above 21 years old and did not use the drug for 8 weeks. Did not participate in other research projects. Exclusion criteria: if a patient is suffering from an infectious disease or fever in last month or is taking antibiotics are excluded

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Street address
yazd-sadoughi street

City
yazd

Postal code
۸۹۱۶۹۷۸۴۷۷

Approval date
2013-04-29, 1392/02/09

Ethics committee reference number
20229

Health conditions studied

1

Description of health condition studied
Hemodialysis

ICD-10 code
Z49

ICD-10 code description
Care involving dialysis

2

Description of health condition studied
Malnutrition

ICD-10 code
E40-46

ICD-10 code description
Malnutrition

Primary outcomes

1

Description
pre albumin

Timepoint
First, after 3 months at the end of the study

Method of measurement
blood samples,mg/dl

2

Description
transferin

Timepoint
First, after 3 months at the end of the study

Method of measurement
blood samples,mg/dl

3

Description
total lymphocite count

Timepoint
First, after 3 months at the end of the study

Method of measurement
blood samples,mg/dl

4

Description
pre albumin

Timepoint
First, after 3 months at the end of the study

Method of measurement
blood samples,mg/dl

5

Description
c-reactive protein

Timepoint
First, after 3 months at the end of the study

Method of measurement
blood samples,mg/dl

Secondary outcomes

empty

Intervention groups

1

Description
treatment group, received 1 carnitin oral vial of 1000 mg .
Category
Treatment - Drugs

2

Description
The control group did not receive carnitine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shhid Dr. Rahnamoon hospital
Full name of responsible person
Shima Dehghan
Street address
Yazd. Farrokhi str.
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Science
Full name of responsible person
Hasan Mozaffari
Street address
Daneshjoo Boulevard
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd Shahid Sadoughi University of Medical Science
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
Yazd Shahid Sadoughi University of Medical Science
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Web page address

Person responsible for updating data

Contact

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