

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of carnitine supplementation on adiponectin and leptin total antioxidant capacity concentrations in hemodialysis patients

Protocol summary

Summary

Chronic renal failure is a pathological process with multiple causes. More than a million people die annually due to the end stage renal disease. The most important cause of mortality in ESRD and hemodialysis patients is cardio vascular disease. Common causes to some extent higher risk factor for cardiovascular disease in hemodialysis patients. Several cytokines and hormones (so called adiponectin) are secreted from fat tissue, TNF, leptin, adiponectin, visfatin, resistin. The level of leptin is increased in ESRD and hemodialysis patients. Chronic hemodialysis (HD) frequently encounter carnitin depletion. Carnitin has anti-inflammatory and anti-oxidant properties. person who are enrolled must be over 21 years old and they have passed one year of dialysis. 50 hemodialysis patients from dialysis centers allocate and divide in to groups. 1-intervention group :they receive 1 gram of carnitine daily for 3 month ,2-control group : they do not receive supplement. level of leptin ,adiponectin and TAC are measured at the beginning and the end of study. The aim of study is evaluate the effect of carnitin supplementation on level of leptin and adiponectin and TAC in hemodialysis patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070913160N2**

Registration date: **2013-11-06, 1392/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-06, 1392/08/15

Registrant information

Name

Shima Dehghan

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Department of Nutrition, Department of Public Health, Yazd University of Medical Sciences

Expected recruitment start date

2013-10-06, 1392/07/14

Expected recruitment end date

2013-11-07, 1392/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of carnitine supplementation on adiponectin and leptin total antioxidant capacity concentrations in hemodialysis patients

Public title

The effect of carnitin supplementation in hemodialysis patients

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: patients on hemodialysis in last year; age older than 21 years old and did not take antibiotics; vitamin C, vitamin E, carnitine during last 8 weeks.

Exclusion criteria: if a patients suffering from an infection disease or fever in last month or is taking antibiotics.

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

Gender
Both

Phase
N/A

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

Yazd University of Medical Sciences

Street address

yazd, Bahonar squar, Central organization of Yazd
University of Medical Sciences

City

Yazd

Postal code

Approval date

2013-06-17, 1392/03/27

Ethics committee reference number

52310

Health conditions studied

1

Description of health condition studied

Hemodilysis

ICD-10 code

Z49

ICD-10 code description

Care involving dialysis

Primary outcomes

1

Description

Leptin

Timepoint

Baseline, end of thirth month

Method of measurement

ELISA

2

Description

Adiponectin

Timepoint

Baseline, end of thirth month

Method of measurement

ELISA

3

Description

Total anti oxidant capicity

Timepoint

Baseline, end of thirth month

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: take 1 gram L carnitin syroup for 3 months.

Category

Treatment - Drugs

2

Description

Control group: patients do not recieve carnitin supplement or drug.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayed Shohada Dialysis Center

Full name of responsible person

Street address

City

Yazd

2

Recruitment center

Name of recruitment center

Shahid Rahnemoon Dialysis Center

Full name of responsible person**Street address****City**

Yazd

3

Recruitment center

Name of recruitment center

Taamin Ejtemaee Dialysis Center

Full name of responsible person**Street address****City**

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Medical Sciences,yazd

Full name of responsible person

Dr. Hassan Mozaffari Khosravi

Street address

daneshjoo boulevard , shahid sadooghi of medical science,yazd

City

Yazd

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

Yes

Title of funding source

University of Medical Sciences,yazd

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 University of Medical Sciences

Full name of responsible person

Sedigheh Ahmadi

Position

Student of nutrition(MSC)

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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