

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Effects of carnitine , ubiquinone and both on the levels of serum Lp(a) and homocysteine and on the oxidative stress in heodialysis patients

Protocol summary

Summary

Objective: The present study was designed to investigate the effects of supplementation with carnitine and ubiquinone (Q10) to control CVD risk factors in HD patients under treatment with statin drugs. Type of study: Randomized double blind placebo controlled clinical trial. Population study: HD patients Sample size: 52 HD patients (25 women and 27 men; mean age 53.3+14.2 years). Inclusion criteria: 1) Patients under hemodialysis for at least one year; 2) Serum levels of lipoprotein (a) [Lp(a)] >20 mg/dl and homocysteine (Hcy) \geq 15 mg/dl; 3) Willingness to participate and filling up the consent form. Exclusion criteria: 1) Patients with acute or chronic infection; 2) Patients taking carnitine, ubiquinone, vitamins A, E and C during the last month prior to the trial. Intervention: Patients were randomly divided into four groups, each of them received one of the following drugs: A) Carnitine 1000mg intravenously 3 times/week; B) Q10, 100 mg orally everyday; C) Carnitine+Q10; D) Placebo (n=13). Duration: 3 months Measurements: Fasting blood samples were collected at the beginning and at the end of trial for measuring serum levels of Lp(a), Hcy and malondialdehyde (MDA). Primary outcomes: Carnitine and/or Q10 supplementation may reduce serum levels of Lp(a), Hcy and MDA in HD patients under treatment with statin drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811212779N2**
Registration date: **2010-04-15, 1389/01/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-15, 1389/01/26

Registrant information

Name

Fereydoun Siassi

Name of organization / entity

School of Public Health, Tehran University of Medical Sciences

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siassif@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences and Health Services (TUMS)

Expected recruitment start date

2007-08-23, 1386/06/01

Expected recruitment end date

2007-11-21, 1386/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of carnitine , ubiquinone and both on the levels of serum Lp(a) and homocysteine and on the oxidative stress in heodialysis patients

Public title

Effects of carnitine , ubiquinone and both on the levels of serum Lp(a) and homocysteine and on the oxidative stress in heodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients under hemodialysis for at least one year; 2. Serum levels of Lp(a) >20 mg/dl and homocysteine =>15 mg/dl; 3. Willingness to participate and filling up the consent form. Exclusion criteria: 1. Patients with acute or chronic infection; 2. Patients taking carnitine, ubiquinone, vitamins A,E and C during the last month prior to the trial.

Age

From **20 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

Ethics Committee; Vice Chancellor for Research;
Tehran University of Medical Sciences and Health Ser

Street address

Ghods St., Keshavarz Blvd.

City

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Postal code

1417653761

Approval date

2007-03-19, 1385/12/28

Ethics committee reference number

4956-27-04-85

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

N18

ICD-10 code description

Chronic renal failure

Primary outcomes

1

Description

cardio-vascular risk factors

Timepoint

Before and after 3 months after intervention

Method of measurement

Serum levels of Lp(a) (Elisa); homocysteine (Enzymatic cycling); and malondialdehyde (spectrophotometry).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Carnitine (1000mg iv, 3x/week)

Category

Treatment - Drugs

2

Description

Intervention: Ubiquinone (100mg/day, oral)

Category

Treatment - Drugs

3

Description

Intervention: Carnitine (1000mg iv, 3x/week) and ubiquinone (100mg/day, oral)

Category

Treatment - Drugs

4

Description

Control: saline (5cc iv, 3x/week) and lactose (100mg/d, oral)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital, Tehran

Full name of responsible person

Dr. Seyed Mohammad Reza Khatami

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Imam-Khomeini Hospital, Keshavarz Blvd.,

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hatef663@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Tehran University of
Medical Sciences and Health Services

Full name of responsible person

Dr. Akbar Fotouhi

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Ghods St., Keshavarz Blv., Uni Administration Bldg,
6th floor

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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

Vice Chancellor for Research, Tehran University of
Medical Sciences and Health Services

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**

School of Public Health; Tehran University of Medical
Sciences and Health Services (TUMS)

Full name of responsible person

Dr. Mir-Hatef Shojaei

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PhD student

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Web page address**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