# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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) ≥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**

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Fereydoun Siassi
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**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 yer; 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**
Tehran
**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 (spectophotometry).

## 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

**Street address**
Imam-Khomeini Hospital, Keshavarz Blvd.,
**City**
Tehran

## 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
**Street address**
Ghods St., Keshavarz Blv., Uni Adminstration Bldg, 6th floor
**City**
Tehran
**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*