

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8895 4924

###### Email address

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

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 (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

**Street address**

Imam-Khomeini Hospital, Keshavarz Blvd.,

**City**

Tehran

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

**Street address**

Ghods St., Keshavarz Blv., Uni Administration 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****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

**Position**

PhD student

**Other areas of specialty/work****Street address**

Department of Nutrition and Biochemistry, School of  
Public Health, TUMS; P.O.Box 14155-6446

**City**

Tehran

**Postal code****Phone**

+98 21 8897 3903

**Fax**

+98 21 8898 9132

**Email****Person responsible for scientific  
inquiries****Contact****Name of organization / entity**

School of Public Health, Tehran University of Medical  
Sciences and Health Services

**Full name of responsible person**

Dr. Fereydoun Siassi

**Position**

Professor/Ph.D.

**Other areas of specialty/work****Street address**

Department of Nutrition and Biochemistry, School of  
Public Health, TUMS; P.O.Box 14155-6446

**City**

Tehran

**Postal code****Phone**

+98 21 8895 4924

**Fax**

+98 21 8898 9132

**Email**

siassif@tums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

School of Public Health, Tehran University of Medical  
Sciences and Health Services

**Full name of responsible person**

Dr. Mir-Hatef Shojaei

**Position**

Student/PhD

**Other areas of specialty/work****Street address**

Dept. of Nutrition and Biochemistry, School of Public  
Health, TUMS; P.O.Box 14155-6446

**City**

Tehran

**Postal code****Phone**

+98 21 8897 3903

**Fax****Email**

hatef663@yahoo.com

**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*