

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Effects of alpha lipoic acid supplementation on serum level of visfatin, markers of oxidative stress, inflammation and insulin resistance in patients with chronic renal failure undergoing hemodialysis.

#### Protocol summary

##### Summary

The main purpose of this study is to evaluate the effects of alpha lipoic acid supplementation on serum level of visfatin, markers of oxidative stress, inflammation, and insulin resistance in patients with chronic renal failure undergoing hemodialysis. 60 patients with ESRD who are on hemodialysis for more than 6 months and receive 3 times hemodialysis each week will be included in this study and randomly assigned into the treatment group receiving 600 mg/day of alpha lipoic acid for 8 weeks, or the control group receiving placebo. 24 hrs recalls for 2 days (dialysis and non dialysis day) will be recorded at the baseline and after 8 weeks. Fasting blood samples will be obtained at the baseline and after 8 weeks. Cholesterol, TG, HDL, FBS, and TAC measured by calorimetric method, Visfatin, insulin measured by ELIZA, hsCRP measured by immunoturbidometric method, and MDA measured by fluorimetric method in serum will be measured and compared between groups. HOMA-IR will be calculated by formula and LDL by Friedewald formula.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138806301197N2**

Registration date: **2010-03-20, 1388/12/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-03-20, 1388/12/29

##### Registrant information

###### Name

Reza Mahdavi

##### Name of organization / entity

Faculty of Health & Nutrition, Tabriz Univ. of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Nutritional Research Center Tabriz University Of Medical Sciences; Vice Chancellor for Research, Tabriz University Of Medical Sciences; Drug Applied Research Center Tabriz University Of Medical Sciences

##### Expected recruitment start date

2010-01-20, 1388/10/30

##### Expected recruitment end date

2010-04-19, 1389/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of alpha lipoic acid supplementation on serum level of visfatin, markers of oxidative stress, inflammation and insulin resistance in patients with chronic renal failure undergoing hemodialysis.

##### Public title

Effects of alpha lipoic acid supplementation on serum level of visfatin, markers of oxidative stress, inflammation and insulin resistance in patients with chronic renal failure undergoing hemodialysis.

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: obtaining informed consent, being on hemodialysis for more than 6 months, receiving 3 times hemodialysis each week Exclusion criteria: hepatitis and other infections less than 20 years, receiving any NSAID and SAID, alpha lipoic acid supplement, vitamin C, vitamin E, valproic acid in the month prior to the study, presence of gastrointestinal disorders, being candidate for kidney transplantation, pregnancy or lactation, smoking, possibility of any side effect for consumption of the supplement

## Age

From **20 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## 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

The Research Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences

##### City

Tabriz

##### Postal code

#### Approval date

2009-10-05, 1388/07/13

#### Ethics committee reference number

886

## Health conditions studied

### 1

#### Description of health condition studied

chronic renal failure

#### ICD-10 code

N18.0

#### ICD-10 code description

End-stage renal disease

## Primary outcomes

### 1

#### Description

visfatin

#### Timepoint

baseline and after 8 weeks

#### Method of measurement

ELIZA

### 2

#### Description

TAC

#### Timepoint

baseline and after 8 weeks

#### Method of measurement

calorimetric method

### 3

#### Description

MDA

#### Timepoint

baseline and after 8 weeks

#### Method of measurement

flurimetric method

### 4

#### Description

hsCRP

#### Timepoint

baseline and after 8 weeks

#### Method of measurement

immunoturbidometric method

### 5

#### Description

fasting insulin

#### Timepoint

baseline and after 8 weeks

#### Method of measurement

ELIZA

### 6

#### Description

fasting Glu

#### Timepoint

baseline and after 8 weeks

#### Method of measurement

calorimetric method

## 7

### **Description**

HOMA-IR

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

formula

## 8

### **Description**

Tchol

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

calorimetric method

## 9

### **Description**

serum TG

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

calorimetric method

## 10

### **Description**

serum HDL-c

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

calorimetric method

## 11

### **Description**

serum LDL

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

Friedelwald formula

## 12

### **Description**

Body Mass Index (BMI)

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

calculation

## 13

### **Description**

Total Daily Calorie

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

24h recalls

## 14

### **Description**

Daily protein

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

24h recalls

## 15

### **Description**

Daily Fat

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

24h recall

## 16

### **Description**

Daily carbohydrate

### **Timepoint**

baseline and after 8 weeks

### **Method of measurement**

24h recall

## 17

### **Description**

Update 19 Feb 2011: serum albumin

### **Timepoint**

Update 19 Feb 2011: baseline and after 8 weeks

### **Method of measurement**

Update 19 Feb 2011: Bromocresol Green method

## **Secondary outcomes**

### 1

#### **Description**

health benefits for patients

#### **Timepoint**

baseline and weekly monitoring

#### **Method of measurement**

observation and evaluation of biochemical parameters

## **Intervention groups**

### 1

#### **Description**

Daily consumption of alpha lipoic acid capsule (600 mg) for 8 weeks

#### **Category**

*empty*

### 2

#### **Description**

daily consumption of placebo for 8 weeks

#### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Hemodialysis centers in Tabriz  
**Full name of responsible person**  
Reza Mahdavi  
**Street address**  
Tabriz University Of Medical Science  
**City**  
Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Nutritional Research Center Tabriz University Of  
Medical Science  
**Full name of responsible person**  
Ali Reza Ostadrahimi  
**Street address**  
Tabriz University Of Medical Sciences  
**City**  
Tabriz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Nutritional Research Center Tabriz University Of Medical  
Science  
**Proportion provided by this source**  
**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*

2

### Sponsor

**Name of organization / entity**  
Vice Chancellor for Research, Tabriz University Of  
Medical Science  
**Full name of responsible person**  
Ali Reza Ostadrahimi  
**Street address**  
Tabriz University Of Medical Sciences  
**City**  
Tabriz  
**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, Tabriz University Of  
Medical Science  
**Proportion provided by this source**  
**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*

3

### Sponsor

**Name of organization / entity**  
Drug Applied Research Center Tabriz University Of  
Medical Sciences  
**Full name of responsible person**  
Hossein Babaei  
**Street address**  
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**City**  
Tabriz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
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Yes  
**Title of funding source**  
Drug Applied Research Center Tabriz University Of  
Medical Sciences  
**Proportion provided by this source**  
**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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**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*