

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

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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
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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
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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