

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effects of Alpha-Lipoic Acid Supplementation on serum TNF alpha and IL-8 in hemodialytic patients.

Protocol summary

Summary

Cardiovascular diseases are the most common causes of mortality among CKD patients. This is essentially due to chronic inflammation. Alpha lipoic acid (ALA) is a potential anti-inflammatory agent and may have some benefits in dialytic patients. Our study is a double blind randomized clinical trial on 60 ESRD patients in Tabriz city that divided into 2 groups (each group 30 patients) that receive 800 mg ALA or placebo orally for 60 consecutive days respectively. Serum TNF- α and IL-8 level would be measured in the beginning and after 60 days of trial and analyzed by proper analytic methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051813360N1**
Registration date: **2013-06-07, 1392/03/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-07, 1392/03/17

Registrant information

Name

Javid Safa

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 4652

Email address

drsafa2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Chronic Kidney Diseases research center, Tabriz
University of Medical Sciences

Expected recruitment start date

2013-06-01, 1392/03/11

Expected recruitment end date

2013-08-10, 1392/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Alpha-Lipoic Acid Supplementation on serum TNF alpha and IL-8 in hemodialytic patients.

Public title

Antioxidant effects of alpha lipoic acid on dialytic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: 1-acceptance and compliance of patients 2- history of 6 months hemodialysis or more 3- 3 session of hemodialysis every week Exclusion:1- hepatitis B and any active infection 2-Age<20 3-non steroid anti-inflammatory drugs, steroid,Vitamin-C, Vit E, Valproat Na use 4- Smoking 5- Advers reaction and sensitivity to alpha lipoic acid 6- Gastrointestinal disorders 7- pregnancy and breast feeding 8- candidates for recent kidney transplantation (less than 1 month)

Age

From **20 years** old to **100 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**

Tabriz University of Medical Sciences

Street address

Daneshgah Avenue

City

Tabriz

Postal code**Approval date**

2013-05-20, 1392/02/30

Ethics committee reference number

9230

Health conditions studied**1****Description of health condition studied**

Chronic Kidney Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5 on dialysis

Primary outcomes**1****Description**

interleukin-8

Timepoint

Time zero and 60 days after intervention

Method of measurement

ELISA kit

2**Description**

TNF-alpha

Timepoint

Time zero and 60 days after intervention

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups**1****Description**

administration of 600 mg alpha lipoic acid capsule orally for 60 consecutive days.

Category

Treatment - Other

2**Description**

administration of placebo capsules orally for 60 consecutive days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

29 Bahman hospital

Full name of responsible person

Mrs. Roghayeh Mosleh manager of dialysis ward

Street address**City**

Tabriz

2**Recruitment center****Name of recruitment center**

Sina general hospital

Full name of responsible person**Street address****City**

Tabriz

3**Recruitment center****Name of recruitment center**

Shahid madany hospital

Full name of responsible person**Street address****City**

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Ardalan Chief of chronic kidney diseases research center

Street address

Imam Reza hospital

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz university of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Javid Safa

Position

Assistant professor of nephrology

Other areas of specialty/work

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Person responsible for scientific inquiries

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MD, Internal medicine resident

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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