

# 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- $\alpha$  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, Valproate Na use 4- Smoking 5- Adverse 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

### Contact

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**Position**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Maryam Pourkar Jadid

**Position**

MD, Internal medicine resident

**Other areas of specialty/work**

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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*