

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of alpha-lipoic acid supplementation on some cardiovascular indicators, inflammatory markers, and lipid profile in patients with stroke

#### Protocol summary

##### Summary

aim: The effect of alpha-lipoic acid supplementation on some cardiovascular indicators, inflammatory markers, and lipid profile in patients with stroke Study design: double blind, randomized and placebo-controlled clinical trial, Inclusion criteria: patients with thrombotic and embolic stroke; NIH Score = 5-24 ; age 30 to 70 years; BMI in the range of 18.5-35. exclusion criteria: unwillingness to continue; recurrent stroke during the study; death. Sample size: 80 Intervention: 600mg lipoic acid or placebo for 12 weeks Primary outcomes: Carotid Intima Media Thickness, Flow Mediated Dilation, Interleukin -6, Tumor Necrosis Factor-alpha, hs-CRP, systolic and diastolic blood pressure, triglycerides, total cholesterol, LDL- cholesterol, HDL- cholesterol, Fasting Blood Sugar, fasting insulin

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016051811763N23**

Registration date: **2016-06-29, 1395/04/09**

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

Last update:

Update count: **0**

##### Registration date

2016-06-29, 1395/04/09

##### Registrant information

###### Name

Gholamreza Askari

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2110

###### Email address

askari@mui.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice President of Research, Isfahan university of Medical sciences

###### Expected recruitment start date

2016-05-21, 1395/03/01

###### Expected recruitment end date

2016-10-22, 1395/08/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effect of alpha-lipoic acid supplementation on some cardiovascular indicators, inflammatory markers, and lipid profile in patients with stroke

###### Public title

The effect of lipoic acid supplementation on stroke patients

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: patients with thrombotic and embolic stroke ; NIH Score = 5-24 ; age 30 to 70 years; BMI in the range of 18.5-35. exclusion criteria: unwillingness to continue; recurrent stroke during the study; death.

###### Age

From **30 years** old to **70 years** old

###### Gender

Both

###### Phase

2-3

### Groups that have been masked

No information

### Sample size

Target sample size: 80

### 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

Isfahan university of Medical sciences

##### Street address

Vice president of research-Isfahan university of  
Medical sciences- Hezarjarib street- Isfahan

##### City

Isfahan

##### Postal code

#### Approval date

2016-05-09, 1395/02/20

#### Ethics committee reference number

IR.MUI.REC.1395.3.068

## Health conditions studied

### 1

#### Description of health condition studied

strok

#### ICD-10 code

I64

#### ICD-10 code description

Stroke, not specified as haemorrhage or infarction

## Primary outcomes

### 1

#### Description

carotid intima media thickness

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

sonography doppler

### 2

#### Description

flow mediated dilation

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

sonography doppler

### 3

#### Description

TNF- $\alpha$

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

ELISA

### 4

#### Description

IL-6

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

ELISA

### 5

#### Description

hs-CRP

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

ELISA

### 6

#### Description

TG

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

kit

### 7

#### Description

total cholesterol

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

Enzymatic

### 8

#### Description

LDL

#### Timepoint

Before and 12 weeks after intervention

#### Method of measurement

Friedewald

## 9

### **Description**

HDL

### **Timepoint**

Before and 12 weeks after intervention

### **Method of measurement**

Spectrophotometry

## 10

### **Description**

Fasting blood glucose

### **Timepoint**

Before and 12 weeks after intervention

### **Method of measurement**

Spectrophotometry

## 11

### **Description**

fasting insulin

### **Timepoint**

Before and 12 weeks after intervention

### **Method of measurement**

ELISA

## 12

### **Description**

systolic blood pressur

### **Timepoint**

Before and 12 weeks after intervention

### **Method of measurement**

Mercury manometers

## 13

### **Description**

diastolic blood pressur

### **Timepoint**

Before and 12 weeks after intervention

### **Method of measurement**

Mercury manometer

## **Secondary outcomes**

## 1

### **Description**

carotenoids intake

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

24 food recall

## 2

### **Description**

weight

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

seca balance

## 3

### **Description**

waist circumference

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

tape

## 4

### **Description**

energy intake

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

24 food recall

## 5

### **Description**

carbohydrate intake

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

24 food recall

## 6

### **Description**

fat intake

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

24 food recall

## 7

### **Description**

protein intake

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

24 food recall

## 8

### **Description**

vitamin E intake

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

24 food recall

## 9

### **Description**

vitamin C intake

### **Timepoint**

before and 12 weeks after intervention

### **Method of measurement**

24 food recall

## Intervention groups

1

### Description

lipoic acid 600 mg

### Category

Treatment - Drugs

2

### Description

corn starch 600 mg

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Al Zahra Hospital

#### Full name of responsible person

Vida Mohammadi

#### Street address

#### City

Isfahan

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice President of Research, Isfahan University of Medical Sciences

#### Full name of responsible person

Amirmansour Alavi

#### Street address

Hezarjarib street

#### City

Isfahan

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vice President of Research, Isfahan 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

Isfahan University of Medical Sciences

#### Full name of responsible person

Vida Mohammadi

#### Position

PhD candidate

#### Other areas of specialty/work

#### Street address

Hezarjarib street, Isfahan University of Medical Sciences

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#### Fax

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Mohammadi\_vida@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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Gholam Reza Askari

#### Position

PhD of Nutrition sciences

#### Other areas of specialty/work

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## Person responsible for updating data

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**Fax**

**Email**

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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*