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; NIHS 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 Suger, 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

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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 ; NIHS 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-α

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 weeksafter 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
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Person responsible for updating data

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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