

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effects of alpha-lipoic acid supplementation on oxidative stress status, inflammatory markers, VCAM-I serum levels, lactate and clinical symptoms in women with migraine.

Protocol summary

Study aim

The effect of alpha-lipoic acid supplementation on the clinical symptoms of migraine, serum lactate levels, vascular adhesion molecule, oxidative status, nitric oxide, in women with migraine

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment.

Settings and conduct

Participants will be selected from among women with migraines who go to the special clinic of Imam Musa Sadr Hospital in Isfahan. According to the case file of the sick people, the patients will be examined according to the criteria for entering the study and the people who have the conditions to participate in the study will enter the study. The study was two-way blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Willingness to participation in the study; 2) Diagnosis of migraine by a neurologist based on ICHD-3 criteria. 3) Age 20 to 50 years. Exclusion criteria: 1) History of any allergies, intolerances or harmful drug reactions to the supplement under study 2) History of intestinal bypass.

Intervention groups

Patients in the intervention group will receive 300 mg alpha-lipoic acid twice a day and control group will receive placebo.

Main outcome variables

The effects of Alpha-lipoic acid supplement on clinical signs of migraine (severity, frequency and duration), MHI, HIT-6, Nitric oxide, Lactate, VCAM-I, Oxidative status, in woman with migraine is assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161203031212N3**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-05, 1400/01/16**

Update count: **1**

Registration date

2020-11-09, 1399/08/19

Registrant information

Name

Forugh Fasihi

Name of organization / entity

Isfahan University of Medical Sciences, School of Nutrition and Food Sciences, Dept

Country

Iran (Islamic Republic of)

Phone

+98 21 4426 7331

Email address

am.alavi@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of alpha-lipoic acid supplementation on oxidative stress status, inflammatory markers, VCAM-I serum levels, lactate and clinical symptoms in women with migraine.

Public title
The effect of alpha-lipoic acid on migraine.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Willingness to participation in the study. Diagnosis of migraine by a neurologist based on ICHD-3 criteria. Age 20 to 50 years. Non-menopausal women.
Exclusion criteria:
 History of any allergies, intolerances or adverse drug reactions to the supplement. Pregnancy and lactation. History of intestinal bypass. Follow a special diet for the past 6 months. Smoking or alcohol. Take any supplements. Cardiovascular disease, diabetes, liver, kidney, thyroid, malignant disease and other neurological disorders are diagnosed based on the patient interview. Start taking the new drug within the last 1 month

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects. Randomization within each block will be done based on a table of random numbers using a valid random number generation website. Reputable website for generating random numbers:
<https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)
Double blinded

Blinding description
Supplementary and placebo packages will be prepared and coded by Raha Pharmaceutical Company and are completely the same in terms of all appearance, color, smell and label, and each patient is randomly assigned a number using the order obtained from the reputable website. And the researcher and patients will not be informed of the contents of the packages until the end of the study.

Placebo

Used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.436

Health conditions studied

1

Description of health condition studied

migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Migraine severity

Timepoint

At baseline and after 3 month.

Method of measurement

Visual analogue scale

2

Description

Migraine frequency .

Timepoint

At baseline and after 3 month.

Method of measurement

Clinical examination.

3

Description

Migraine duration

Timepoint

At baseline and after 3 month.

Method of measurement

Clinical examination.

4

Description

Headache impact test

Timepoint

At baseline and after 3 month.

Method of measurement

HIT questionnaire

5

Description

C-reactive protein (CRP)

Timepoint

At baseline and after 3 month.

Method of measurement

Colorimetric method.

6

Description

Serum glutathion

Timepoint

At baseline and after 3 month.

Method of measurement

Colorimetric method.

7

Description

Total antioxidant capacity

Timepoint

At baseline and after 3 month.

Method of measurement

Colorimetric method.

8

Description

Total oxidant capacity

Timepoint

At baseline and after 3 month.

Method of measurement

Colorimetric method.

9

Description

Malondialdehyde

Timepoint

At baseline and after 3 month.

Method of measurement

Colorimetric method.

Secondary outcomes

1

Description

vascular cell adhesion molecule-1

Timepoint

At baseline and after 3 month.

Method of measurement

It will be measured by ELISA kit.

2

Description

Serum lactate

Timepoint

At baseline and after 3 month.

Method of measurement

Colorimetric method.

3

Description

Serum Nitric Oxide

Timepoint

At baseline and after 3 month.

Method of measurement

Colorimetric method.

4

Description

Depression

Timepoint

At baseline and after 3 month.

Method of measurement

DASS questionnaire

5

Description

Anxiety

Timepoint

At baseline and after 3 month.

Method of measurement

DASS questionnaire

6

Description

Stress

Timepoint

At baseline and after 3 month.

Method of measurement

DASS questionnaire.

Intervention groups

1

Description

People will receive 300 mg of alpha-lipoic acid supplement twice a day for 3 months. The supplement

and placebo will be provided by Raha Pharmaceutical Company.

Category

Treatment - Other

2

Description

The control group will receive an alpha-lipoic acid placebo twice daily for 3 months. Supplements and placebo will be provided by Raha Pharmaceutical Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Musa Sadr Clinic in Isfahan

Full name of responsible person

Dr. Fariborz Khorvash neurologist

Street address

Foroughi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoi Javanmard

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Hezarjarib Ave

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Amir Mansour Alavi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Dr Amir Mansour Alavi

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Assistant Professor

Latest degree

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Person responsible for updating data

Contact

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Full name of responsible person
Mahnaz Rezaei
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PhD student
Latest degree
Master
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Nutrition
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Hezarjarib Ave
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Isfahan

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available