

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effect of Enalapril on endothelial dysfunction and improvement of clinical status in migraineurs

Protocol summary

Summary

The goal of this study was to evaluate the role of Enalapril as an ACE inhibitor on the improvement of headache attacks and clinical status of migraineurs and also on endothelial function as a possible mechanism of their disease. 40 migraineurs were enrolled in this clinical trial study. Migraine were diagnosed on the basis of IHS (international headache society) criteria. Patients were randomized to receive either Enalapril 5mg twice a day or placebo. FMD, blood nitrite, nitrate and CRP as markers of endothelium function and also frequency, severity and duration of headaches using a questionnaire will be measured at baseline and two months after intervention and compared between two groups. After receiving testimonial and 5cc blood, FMD will be measured in both patients and healthy groups. The bloods will transfer to -70c freezer for later nitrite & nitrate & CRP measurement. Second step: The migraineurs will complete a questionnaire about frequency, severity & duration of their headaches. Then we'll randomize the patients in case and control group. Case and control groups will receive 5 mg Enalapril or placebo twice a day for 2 months respectively. After these 2 months the FMD will be measured and 5cc blood will obtain from all of the patients. They should be fast for at least 15 hours before these procedures. All of the data will be measured by the same instruments as before. Again, the migraine questionnaire will complete by patients according to their headaches in these two months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711011570N1**

Registration date: **2009-09-26, 1388/07/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-09-26, 1388/07/04

Registrant information

Name

Shaghayegh Haghjooy Javanmard

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2008-08-01, 1387/05/11

Expected recruitment end date

2009-07-01, 1388/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Enalapril on endothelial dysfunction and improvement of clinical status in migraineurs

Public title

Evaluation of the effect of Enalapril on endothelial dysfunction and improvement of clinical status in migraineurs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: having more than three migraine attacks per month during the last 3 months, having more than 3 migraine attacks during the baseline period, debut of migraine at least one year prior to study, start of migraine before age 50 years Exclusion Criteria: Having cardiovascular (endothelial dysfunction) risk factors, undistinguishable headache interval from migraine, chronic tension-type headache or other headache occurring on more than 15 days per month, pregnancy, breast feeding, inability to use contraceptives, presence of heart conduction block on ECG or significant ECG abnormality, presence of current or previous asthma, diabetes, decreased hepatic or renal function, hypersensitivity to active substance, significant psychiatric illness, use of daily migraine prophylactics less than 4 weeks prior to study, having tried more than or equal to three prophylactic drugs against migraine during the last 10 years, previous use of Enalapril in adequate doses, previous discontinuation of Enalapril due to side effects, current use of antihypertensive medication, subjects requiring detoxification from acute medication (Ergotamines, Opioids), consistently failure to respond to any acute migraine medication, alcohol or illicit drug dependence

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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

Applied physiology research center, Isfahan

University of Medical Sciences,

City

Esfahan

Postal code

81745

Approval date

2008-12-09, 1387/09/19

Ethics committee reference number

p12/4/1/251

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Diseases of the nervous system/Episodic and paroxysmal disorders

Primary outcomes

1

Description

Clinical status improvement

Timepoint

before intervention/1 month later/2 months later

Method of measurement

Questionnaire

2

Description

Endothelial dysfunction recovery

Timepoint

before intervention/2 months later

Method of measurement

FMD with high resolution Bmode Ultrasonographic system/NOx with Greiss method/CRP with ELISA

Secondary outcomes

1

Description

Headache frequencies

Timepoint

Before intervention,1 month, 2 month

Method of measurement

Questionnaire

2

Description

Headache durations

Timepoint

Before intervention,1 month, 2 month

Method of measurement

Questionnaire

3

Description

Headache severity

Timepoint

Before intervention, 1 month, 2 month

Method of measurement

Questionnaire

4

Description

FMD Index

Timepoint

Before intervention, 2 months later

Method of measurement

High resolution Bmode Ultrasonography

5

Description

Level of CRP

Timepoint

Before intervention, 2 months later

Method of measurement

ELISA

6

Description

NOx

Timepoint

before intervention, 2 months later

Method of measurement

Greiss method

Intervention groups

1

Description

Enalapril, 5 mg tablet, twice a day for 2 months

Category

Treatment - Drugs

2

Description

Oral placebo tablet, twice a day for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology clinic of al-zahra hospital, Isfahan
University of Medical Sciences

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Applied
Physiology Research Center

Full name of responsible person

Shaghayegh Haghjooie-javanmard

Street address

Isfahan University of Medical Sciences, Hezarjarib st.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences, Applied
Physiology Research Center

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

Shaghayegh Haghjooie-javanmard

Position

Assistant professor/PhD.MD

Other areas of specialty/work

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inquiries

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Full name of responsible person

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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