Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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. Migrain 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

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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 Haghjooiejavanmard
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 Haghjooi-e-javanmard
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inquiries

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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