Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigation of the prophylactic effects of lisinopril in comparison to placebo on chronic migraine

Protocol summary

Summary

In this study we aim at investigating efficacy of prophylactic Lisinopril, an inhibitor ACE, in comparison with placebo in the alleviation of migraine headaches in patients with chronic migraine in a randomized, double-blind. The main objective of the study is to explore the effects of prophylactic Lisinopril vs. placebo in reducing the frequency and severity of chronic headache in migraineurs referred to specialized clinics. Other study objectives include comparing the effects of Lisinopril and placebo in reducing the use of medications during attacks, remission from chronic migraine to episodic migraine, improving migraine associated complications, and improving quality of life in the patients. 112 patients with chronic migraine will be recruited in a randomized double-blind clinical trial. After obtaining the informed consent form from patients, they will be randomly allocated to placebo group or Lisinopril 10 mg taking group. Patients will be included in the study due to the following inclusion Criteria: having ≥ 15 headache days per month for at least 3 months, history of migraine for at least 1 year, age 18-45 years, systolic blood pressure between 110-140 mmHg and taking a large amount of abortive drugs. . The exclusion criteria were as follows: having psychiatric illness, having major neurological disorders and / or other chronic or systemic diseases, being pregnant or have a planned pregnancy, breastfeeding, taking prophylactic medications in the last 4 weeks, suffering from impaired liver function or kidney disorders, allergies to ACE inhibitors, history of angionearotic edema and suffering from secondary headaches. will be asked not to continue any previous medication for migraine . At the same time with prophylactic treatment (lisinopril or placebo) in both groups, 4 capsules of Celebrex 100-milligram per day, thereafter the dosage will be reduced by 100-mg (1 capsule) each 5-day to zero over the first 20 days of the study. Duration of the study will be 12 weeks and headache characteristics as well as drug response and quality of life will be assessed in the second week and at the end of each month during the study.

General information

Acronym

Prophylactic effects of lisinopril on chronic migraine

IRCT registration information

IRCT registration number: **IRCT201701089157N5**
Registration date: **2017-06-14, 1396/03/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-14, 1396/03/24

Registrant information

Name

Prof Mansoureh Togha

Name of organization / entity

Neurology department, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 2052

Email address

toghae@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iranian Center of Neurological Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-06-20, 1396/03/30

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the prophylactic effects of lisinopril in comparison to placebo on chronic migraine

Public title
Investigation of the prophylactic effects of lisinopril on chronic migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Patients will be included in the study due to the following inclusion Criteria: having ≥ 15 headache days per month for at least 3 months, history of migraine for at least 1 year, age 18-45 years, systolic blood pressure between 110-140 mmHg Taking a large amount of abortive drugs. The exclusion criteria were as follows: having psychiatric illness, having major neurological disorders and / or other chronic or systemic diseases, being pregnant or have a planned pregnancy, breastfeeding, taking prophylactic medications in the last 4 weeks, suffering from impaired liver function or kidney disorders, allergies to ACE inhibitors, history of angionearotic edema suffering from secondary headaches.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **112**
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
Tehran University of Medical Sciences
Street address
Qhods St., Keshavarz Boulevard
City
tehran
Postal code
Approval date
2017-01-07, 1395/10/18
Ethics committee reference number
IR.TUMS.VCR.REC.1395.1418

Health conditions studied

1

Description of health condition studied
migraine
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
migraine headache severity
Timepoint
first month, second month, third month
Method of measurement
Visual Analog Scale (VAS)

2

Description
Migraine headache duration
Timepoint
first month, second month, third month
Method of measurement
Migraine headache diary

3

Description
Migraine headache frequency
Timepoint
first month, second month, third month
Method of measurement
Migraine headache diary

Secondary outcomes

1

Description
Remission from Chronic Migraine to Episodic Migraine
Timepoint
first week, second month
Method of measurement
physical examination, headache diary

Intervention groups

1

Description

After the eligibility criteria will be applied, 112 chronic migraineurs will be selected and randomly allocated to placebo or intervention groups. Upon admission, a headache questionnaire will be given to all patients to fill out the characteristics of headaches experienced in the past month (including severity and duration of each attack). Also they will be asked not to take any medication for migraine prophylaxis and or analgesic drugs. Patients in the intervention group (n=56) will be instructed to take a tablet of Lisinopril 5 mg per day at the first week and to use 1 tablet each 12-hour thereafter (2 tablets per day from the second week to the end of the 12th week). At the same time from the beginning of the study, 4 capsules of Celebrex 100-milligram per day, thereafter the dosage will be reduced by 100-mg (1 capsule) each 5-day to zero over the first 20 days of the study. In the second week of the study the patients will be physically examined. Duration of the study will be 12 weeks and headache characteristics as well as drug response and quality of life will be assessed at the end of each month during the study.

Category

Treatment - Drugs

2

Description

After the eligibility criteria will be applied, 112 chronic migraineurs will be selected and randomly allocated to placebo or intervention groups. Upon admission, a headache questionnaire will be given to all patients to fill out the characteristics of headaches experienced in the past month (including severity and duration of each attack). Also they will be asked not to take any medication for migraine prophylaxis and or analgesic drugs. Patients in the placebo group (n=56) will be instructed to take a tablet of placebo per day at the first week and to use 1 tablet each 12-hour thereafter (2 tablets per day from the second week to the end of the 12th week). At the same time from the beginning of the study, 4 capsules of Celebrex 100-milligram per day, thereafter the dosage will be reduced by 100-mg (1 capsule) each 5-day to zero over the first 20 days of the study. In the second week of the study the patients will be physically examined. Duration of the study will be 12 weeks and headache characteristics as well as drug response and quality of life will be assessed at the end of each month during the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital, headache clinic

Full name of responsible person

Prof. Mansoureh Togha

Street address

Sina hospital, Hasan bad Sq, Imam Khomeini Ave,Tehran Iran

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian Center of Neurological Research, Tehran University of Medical Sciences,

Full name of responsible person

Mrs. Bahareh Pourghaz

Street address

Imam Khomeini Hospital, Iranian Center of Neurological Research, Tehran University of Medical Sciences,

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian Center of Neurological Research, Tehran 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

Sina Hospital, Tehran University of Medical Sciences

Full name of responsible person

Prof. Mansoureh Togha

Position

Professor of Neurology

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work

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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