

# 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  $\geq 15$  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 angioneurotic 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  $\geq 15$  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 angioneurotic 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

##### Street address

Sina Hospital, Hasan Abad Sq., Imam Khomeini Ave.

##### City

tehran

##### Postal code

1136746911

##### Phone

+98 21 6670 2052

**Fax**

+98 21 6634 8553

**Email**

toghae@sina.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Prof. Mansoureh Togha

**Position**

Professor of Neurology

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## Person responsible for updating data

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

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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*