# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Evaluation of citalopram efficacy in prevention of migraine headaches

## Protocol summary

**Study aim**
This study is a double blind clinical trial for evaluation of citalopram on prophylaxis of migraine headaches.

**Design**
Two hundred and twenty six patients with migraine headaches are selected according to international headache society criteria(IHS) and randomly assigned in two groups equally. Available samples are marked by a number and then are assigned in two control and intervention groups randomly by use of the chart of random numbers alternatively . The selection of first patients is by lottery.

**Settings and conduct**
One group of patients take citalopram thirty milligrams daily for two months period at noon and control group take placebo for the same period and same time. All patients are evaluate in the beginning, end of first and second months for headache intensity according to visual analogue scale (VAS) and six points behavioral rating (BRS-6) scales and also headaches frequency in one month and headache duration in hour are evaluated at the beginning and end of second month. Study is a double blind and the examiners ,researchers and patients are not aware of the kind of the taken drug or placebo.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: All patients are between eighteen to forty five years old, with at least three attacks each month for at least six months duration of migraine history.Exclusion criteria: Patients with history of other kind of headaches, depression, asthma, heart and kidney failure. Patients with history of using analgesics and opium in less than one month ago. Patients who are already treating by anti depressants, drugs for migraine prophylaxis, corticosteroids, monoamine oxidases, anti epileptics. Any history of allergy to drugs used in the study.

**Intervention groups**
One group of patients take citalopram thirty milligrams daily for two months at noon and control group take placebo for the same period and same time. Number of patients is equal in both and one hundred and thirteen in each group.

**Main outcome variables**
migraine headache intensity migraine headache frequency migraine headache duration

## General information

**Reason for update**

**Acronym**
citalopram and migraine

**IRCT registration information**
IRCT registration number: **IRCT20161103030680N9**
Registration date: **2018-03-02, 1396/12/11**
Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**
Update count: **0**

**Registration date**
2018-03-02, 1396/12/11

**Registrant information**

**Name**
Siamak Afshinmajd
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 8896 9438
**Email address**
afshin@shahed.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**
Vice chancellor for research . Shahed University

**Expected recruitment start date**
2010-03-20, 1388/12/29

**Expected recruitment end date**
2015-03-20, 1393/12/29

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

**Scientific title**
Evaluation of citalopram efficacy in prevention of migraine headaches

**Public title**
Citaloparam in migraine prophylaxsis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age between 18 to 45. Suffering from migraine headaches according to international headache society criteria(IHS). At least three attack of migraine in one month. History of migraine for at least six months.
**Exclusion criteria:**
Suffering from another type of headaches such as Cluster,Tension,.... . History of Asthma, Renal and Heart failure, Depression, any allergic reaction to drugs used in study or similar drugs. Patients who already take drugs for treatment for migraine. History of using anti depressant, anti epileptics, Analgesics, Corticosteroids, Opium, Monoamine Oxidase, and Non steroidal anti inflammatory agents for other reasons.
**Age**
From **18 years** old to **45 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **226**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
All patients referred to Mostafa Khomeini neurology clinic who fulfilled criteria for study at first are marked by a number an then assigned in two intervention and control groups alternatively by chart of random numbers. Selection of patient for first group is by lottery.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
All drugs and placebos are put in packages with the same shapes and dimensions and after code assignment the main researchers and students receive them. They are not aware of the package contents. Researchers are not aware of patients group. The study design is explained truly for each patient separately and notify that selection of group is randomly without their awareness.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethical committee of Shaded University
**Street address**
Entrance of Tehran - Qom Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
3319118651
**Approval date**
2009-03-18, 1387/12/28
**Ethics committee reference number**
Shahed.REC.1387.7

## Health conditions studied

### 1

**Description of health condition studied**
Migraine headaches
**ICD-10 code**
G-43
**ICD-10 code description**
Migraine without aura (common migraine

### 2

**Description of health condition studied**
Migraine headaches
**ICD-10 code**
G43.1
**ICD-10 code description**
Migraine with aura (classic migraine)

## Primary outcomes

### 1

**Description**
Headache Intensity
**Timepoint**
At the beginning and at the end of first and second month
**Method of measurement**
Visual Analougue Scale, And Six points behavioral rating scale BRS-6

**2**

**Description**
Headache frequency
**Timepoint**
At the beginning and at the end of second month
**Method of measurement**
Number of attacks in one month

**3**

**Description**
Headache duration
**Timepoint**
At the beginning and at the end of second month
**Method of measurement**
Average of headaches duration in hour

## Secondary outcomes

**1**

**Description**
Drug reactions such as skin redness, pruritus, burning sensation,....
**Timepoint**
Immediately after patient alarm
**Method of measurement**
Observation and consultation with proper specialist

## Intervention groups

**1**

**Description**
patients in this group take Citalopram thirty milligrams at noon for two months. Dose escalation is gradually within two weeks.
**Category**
Treatment - Drugs

**2**

**Description**
Cotrol group: Patients take placebo which is provided with the same feature and weight at noon. Duration of treatment is two months.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Mostafa Khomeini Hospital
**Full name of responsible person**
Siamak Afshinmajd
**Street address**
Italia street. Keshavarz Blvd
**City**
Tehran
**Province**
Tehran
**Postal code**
1416643491
**Phone**
+98 21 8896 9438
**Fax**
+98 21 8896 9438
**Email**
safshinmajd@gmail.com
**Web page address**

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahed University
**Full name of responsible person**
Zahra Kiasalari
**Street address**
Entrance of Tehran -Qom Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
3319118651
**Phone**
+98 21 5121 5080
**Email**
kiasalari@shahed.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahed University
**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**
Shahed University
**Full name of responsible person**
Siamak Afshinmajd
**Position**
Associate Professor of Neurology

**Latest degree**
Specialist
**Other areas of specialty/work**
Neurology
**Street address**
Entrance of Tehran -Qom express way, Shahed University
**City**
Tehran
**Province**
Tehran
**Postal code**
3319118651
**Phone**
+98 21 5121 3092
**Fax**
**Email**
safshinmajd@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahed University
**Full name of responsible person**
Siamak Afshinmajd
**Position**
Associate Professor of Neurology
**Latest degree**
Specialist
**Other areas of specialty/work**
Neurology
**Street address**
Italia street, Keshavarz Blvd
**City**
Tehran
**Province**
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**Postal code**
1416643491
**Phone**
+98 21 8896 9438
**Fax**
**Email**
safshinmajd@gmail.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shahed University
**Full name of responsible person**
Siamak Afshin majd
**Position**
Associate Professor of Neurology
**Latest degree**
Specialist
**Other areas of specialty/work**
Neurology
**Street address**
Italia street, Keshavarz Blvd
**City**
Tehran
**Province**
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**Email**
safshinmajd@gmail.com
**Web page address**

## 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**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
Yes - There is 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**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
I will decide later about this item
**When the data will become available and for how long**
In publishable data one year after publication of paper and six months thereafter
**To whom data/document is available**
Academic scientists employed in universities
**Under which criteria data/document could be used**
With mention to researchers name can be used without change. By Email
**From where data/document is obtainable**
Italia street. Keshavarz Blvd. Tehran. IRAN
**What processes are involved for a request to access data/document**
writing letter to the mentioned address .Replay takes maximum three months.
**Comments**
No other explanation