Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 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
Tehran
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
Tehran
Postal code
1416643491
Phone
+98 21 8896 9438
Fax
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