Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of acetazolamide efficacy in migraine headaches in menstrual period

Protocol summary

Study aim

This clinical trial conducted on female patients with migraine headaches which is aggravated in menstrual period in spite of treatment for migraine prophylaxis with aim of finding a proper solution for alleviation of their pain .

Design

This randomized double blind clinical trial is conducted on two intervention and control groups in parallel for three months. Selection of patients with migraine is according to international headache society (IHS) criteria.Patients who against treatment for prophylaxis of migraine feel progress of symptom after selection according mentioned criteria are assigned randomly by the use of chart of random numbers in two group equally and fifty patients in each group. All patients take Nortriptiline 0.6 milligram /kilograms at night and Propranolol one milligram/kilograms/day divided to two equal dose . Patients in intervention group take Acetazolamide two hundred and fifty milligrams three times daily which is started three days before usual time of menstruation in each patient to the end of menstrual period in addition to above mentioned drugs. In control group patients take Placebo with the same figure, dose and period in addition to above mentioned drugs.

Settings and conduct

Study is a double blind clinical trial which will be carry out in neurology clinic of mostafa khomeini hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients are between eighteen to forty-five years old with at least three attacks of headache in one month and at least one year history of migraine.Exclusion criteria: Patients with an abnormal findings in neurological exams unrelated to migraine, use of any other drugs at the beginning of study, other types of head or facial pains, ,menstrual period less than five days and any history of hypersensitivity to Acetazolamide are not permitted.

Intervention groups

All Patients in both study and control groups take Nortriptiline 0.6 milligram /kilograms at night and Propranolol one milligram/kilograms/day divided to two equal dose this dose selection by weight is for patient safety and never more than standard permitted dose. Patients in study group in addition to drugs mentioned above take Acetazolamide two hundred and fifty milligrams three times daily which is started three days before usual time of menstruation in each patient to the end of menstrual period. In control group patients take placebo three times daily with similar figure and weight in the same period similar to intervention period in addition to above mentioned drugs.

Main outcome variables

Headache intensity Headache frequency according to number of attacks in one month Headache duration in hour

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161103030680N8**
Registration date: **2018-02-11, 1396/11/22**
Registration timing: **retrospective**

Last update: **2018-02-11, 1396/11/22**
Update count: **0**

Registration date

2018-02-11, 1396/11/22

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 of research. Shahed University

Expected recruitment start date
2013-08-12, 1392/05/21
Expected recruitment end date
2016-04-09, 1395/01/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of acetazolamide efficacy in migraine headaches in menstrual period

Public title
Migraine in menstrual period
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Migraine headaches according to International headache society criteria At least one year history of migraine headaches At least three attacks of headaches in one month Exacerbation of headaches during menstrual periods Age between eighteen to forty-five years old
Exclusion criteria:
Use of any other drugs at the beginning of study Other types of headaches or facial pain Intolerance or allergy to drugs which are used in study Abnormal neurologic exam which is unacceptable in migraine Menstrual period shorter than five days
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with migraine headache who attend in neurology clinic of Mostafa Khomeini hospital and are selected according to study criteria are given a number and then by use of chart of random numbers are assigned randomly in study and control groups. The group of first patient is selected by lottery.
Blinding (investigator's opinion)
Double blinded
Blinding description
Drugs are inserted in uniform packages and code is assigned. Patients researchers and assessors are not aware of patient group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahed University
Street address
Entrance of Tehran - Qom Highway
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2013-04-10, 1392/01/21
Ethics committee reference number
Shahed.REC.1391.37

Health conditions studied

1

Description of health condition studied
Migraine headaches
ICD-10 code
G43
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

Third day after beginning of treatment with acetazolamide and fifth day of menstruation in both groups.

Method of measurement

Visual Analougue Scale

2

Description

Headache duration

Timepoint

At first day before beginning of treatment and at the end of each treatment episode.

Method of measurement

Mean duration of attacks in hour according to patients claims.

3

Description

Headache Intensity

Timepoint

Third day after beginning of treatment and fifth day of menstruation

Method of measurement

6 Points Behavioral Rating Scale

4

Description

Headache frequency

Timepoint

At first day before beginning of treatment and at the end of each treatment episode

Method of measurement

Number of headache attacks

Secondary outcomes

1

Description

Allergic drug reactions (Pruritus, Redness of skin, Urticaria)

Timepoint

Instantly after alarm of the patient

Method of measurement

Observation, examination and consultation with proper specialist

Intervention groups

1

Description

Control group:Fifty patients with migraine headaches which is aggravated during menstrual periods take Nortriptiline 0.6 milligrams / kilogram at night and Propranolol one milligrams / kilogram per day divided to two equal dose for three months. All patients in this group takes placebo three times daily from three days prior the usual time of menstrual period for each patient to the end of period in addition to above mentioned drugs

Category

Treatment - Drugs

2

Description

Intervention group: Fifty patients with migraine headaches which is aggravated during menstrual periods take Nortriptiline 0.6 milligrams / kilogram at night and Propranolol one milligrams / kilogram per day divided to two equal dose for three months. All patients in this group take Acetazolamide two hundred and fifty milligrams three times daily from three days before the usual time for beginning of menstrual period to the end of period in addition to above mentioned drugs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa khomeini hospital

Full name of responsible person

Siamak Afshinmajd

Street address

Italia street. Keshavarz Blvd

City

Tehran

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1416643491

Phone

+98 21 8896 9438

Email

safshinmajd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Kiasalari

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Tehran

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Phone

+98 21 5121 5080

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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

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary