

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison the Effects of Combined Drugs Acetaminophen, Aspirin, Caffeine With Ibo Profen On Acute Attacks of Migraine Headaches

Protocol summary

Summary

In this study is designed for comparison of two drugs, Ibo profen and Acetaminophen, Aspirin, Caffeine, (AAC) in pain relieve in acute phase of migraine headaches. Sixty patients with migraine headaches according to international headache society criteria (IHS) who attended for treatment of their pain are selected and the study aims and procedures are described for them perfectly. Patients are between twenty to forty-five years old and all have informed consent for the use of analgesics. Patients with gastrointestinal problems, other types of headaches such as cluster or tension, ..., other chronic pains, chronic use of opium or analgesics, past history of psychiatric problems and allergy to drugs are not permitted. All patients take Ibuprofen 800 mg (two tablets of 400 mg) and 2 AAC tablets in four separate attacks of headache. Pain in these patients is measured with point box scale 11 (BS11) before and then 2 and 6 hours after use of drugs in each attack. All patients in first two attack take ibuprofen and take AAC in the third and fourth attack. Patients and the persons who give the drugs to patients blinded to drug type. All patients are evaluated with 6-points behavioral rating scale (BRS-6) which is a clinical scale for pain evaluation only one time six hours after each drug separately. All data are analyzed statically for comparison of effects between to drugs. All patients have written informed consent by supervision of ethical committee of shahed university and can leave the study each time during it.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052930680N4**

Registration date: **2017-10-02, 1396/07/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-02, 1396/07/10

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

Research Department of Shahed University. This Is a Dissertation in General Medicine.

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2017-12-20, 1396/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effects of Combined Drugs
Acetaminophen, Aspirin, Caffeine With Ibo Profen On
Acute Attacks of Migraine Headaches

Public title

The Effect Of Combination of Drugs Acetaminophen,

Aspirin, Caffeine (AAC) on Migraine Headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria; Migraine headache according to criteria of international headache society Informed consent of patients for use of analgesics in acute attack of headaches Age between twenty to forty-five years old Exclusion Criteria; Gastro intestinal problems Other types of headaches such as cluster,tension,.... Chronic pain in other parts of body Chronic use of analgesics or opium Past history of psychiatric problems Allergy to drugs which are used in the study

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Shahed University

Street address

Entrance of Tehran - Qom highway

City

Tehran

Postal code

Approval date

2017-04-05, 1396/01/16

Ethics committee reference number

IR.SHAHED.REC.1395.235

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G-43

ICD-10 code description

MIGRAINE

Primary outcomes

1

Description

Pain

Timepoint

Before, Two and six hours after taking drugs each time and four time for each patient

Method of measurement

BS-11/11-Point box scale/

2

Description

Pain

Timepoint

six hours after taking each drug one time and two time for each patient

Method of measurement

BRS-6/6-point behavioral rating scale

Secondary outcomes

1

Description

Urticaria,Pruritus and redness of skin

Timepoint

Instantly after alarm of the patient

Method of measurement

Observation and consultation with proper specialist

Intervention groups

1

Description

Both test and control are the same .Each migrainous patients takes drugs for four times .At first and second attack iboprofen and acetaminophen,aspirin and caffeine for 3rd and 4th attacks and each time patients are evaluated with standard scales for pain

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

Keshavarz Bld, Italia Street, tehran.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Department, Shahed University

Full name of responsible person

Zahra Kiasalari. Head of Research Department.

Street address

Entrance of Tehran -Qom Highway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Department, Shahed University

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**

Medicine Faculty ,Shahed University

Full name of responsible person

Siamak Afshinmajd

Position

Associate Professor of Neurology

Other areas of specialty/work**Street address**

Entrance of Tehran -Qom express way, Shahed University

City

Tehran

Postal code**Phone**

+98 21 5121 3092

Fax**Email**

afshin@shahed.ac.ir

Web page address**Person responsible for scientific****inquiries****Contact****Name of organization / entity**

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Siamak Afshinmajd

Position

Associate Professor of Neurology

Other areas of specialty/work**Street address**

Keshavarz Bld, Italia Street, Tehran.

City

Tehran

Postal code**Phone**

+98 21 8896 9438

Fax**Email**

safshinmajd@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Siamak Afshinmajd

Position

Associate Professor of Neurology

Other areas of specialty/work**Street address**

Keshavarz Bld, Italia Street, Tehran

City

Tehran

Postal code**Phone****Fax****Email**

safshinmajd@yahoo.com

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