

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparative assessment of Intravenous Magnesium Sulphate vs. Intravenous Caffeine in Acute Migraine Headache Presenting to the Emergency Department

Protocol summary

Summary

Objectives: Comparative assessment of intravenous caffeine citrate vs. intravenous magnesium sulfate intravenous administration efficacy in acute Migraine headaches Inclusion criteria: Moderate to severe pain (pain score>4) in ages 18-60 year old with diagnosis of migraine headache Exclusion criteria: History of Arrhythmia; Ischemic heart disease; Hypertension; Peptic ulcer disease; Inflammatory bowel disease; Obsessive disorder; Pregnancy; Breast feeding period; Homeostasis disorder; Renal failure; Hepatic failure; Sleep disorder Participants: Patients with complaint of moderate to severe headache who are consist with diagnosis of common migraine according to IHS criteria without any contraindication for caffeine and magnesium Sample size: 70 patients Setting and conduct: Eligible patients based on study design (available sampling) after pain assessment with Visual Analog Scale (VAS) will treated with drug administration and reassessed 30min, 1hr and 2hr after. 30 mm (3 score) reduction in measured scale will be acceptable response. Main outcome measures: Pain Score change 30 min, 1 and 2 hours after drug administration

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061315640N2**
Registration date: **2016-07-02, 1395/04/12**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name

Alireza Baratloo

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 0432

Email address

alirezabaratloo@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-09-21, 1395/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of Intravenous Magnesium Sulphate vs. Intravenous Caffeine in Acute Migraine Headache Presenting to the Emergency Department

Public title

Intravenous Caffeine Citrate versus Magnesium Sulphate for Pain control of Acute Migraine Headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Moderate to severe pain (pain score>4)

in ages 18-60 year old; with History of at least five attacks lasts 4 to 72 hours (untreated or unsuccessfully treated) and headache has at least two of the following characteristics: Unilateral location, Pulsating quality, Moderate to severe pain intensity, Aggravation by or causing avoidance of routine physical activity; At least one of the following during headache: Nausea or vomiting (or both), Photophobia and phonophobia; Not attributable to another disorder Exclusion criteria: History of ... Arrhythmia; Ischemic heart disease; Hypertension; Peptic ulcer disease; Inflammatory bowel disease; Obsessive disorder; Pregnancy; Breast feeding period; Homeostasis disorder; Renal failure; Hepatic failure; Sleep disorder

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences, Velenjak Street

City

Tehran

Postal code

Approval date

2014-05-26, 1393/03/05

Ethics committee reference number

IR.SBMU.MSP.REC.1395.134

Health conditions studied

1

Description of health condition studied

Common Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

pain

Timepoint

30 min, 1 and 2 hour after drug administration

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

side effects

Timepoint

from starting drug administration to 2 hours after end

Method of measurement

Serial physical exam

Intervention groups

1

Description

Caffeine citrate 60 mg Intravenously/ slow infusion in 30 min (one time)

Category

Treatment - Drugs

2

Description

Magnesium sulfate 2 g Intravenously/ slow infusion in 30 min (one time)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Dr. Alireza Baratloo

Street address

Tajrish Square

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Hosein Hospital

Full name of responsible person

Dr. Majid Shojaee

Street address

Shahid Madani Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fariba Tadayon

Street address

Velenjak Street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Alireza Baratloo

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

Street address

Emergency Department, Shohadaye Tajrish Hospital,
Tajrish Square

City

Tehran

Postal code

1989934148

Phone

+98 21 2271 8000

Fax

+98 21 2272 1155

Email

alirezabaratloo@yahoo.com;

alirezabaratloo@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Hosein Delavar Kasmayi

Position

Assistant Professor of Neurology

Other areas of specialty/work

Street address

Neurology Department, Shohadaye Tajrish Hospital,
Tajrish Square

City

Tehran

Postal code

1989934148

Phone

+98 21 2271 8000

Fax

+98 21 2272 1155

Email

hdkasmai@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Alireza Baratloo

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

Street address

Emergency Department, Shohadaye Tajrish Hospital,
Tajrish Square

City

Tehran

Postal code

1989934148

Phone

+98 21 2271 8000

Fax

+98 21 2272 1155

Email

alirezabaratloo@yahoo.com;

alirezabaratloo@sbmu.ac.ir

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