

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of intravenous infusion of propofol and sodium valproate on alleviation of acute migraine

Protocol summary

Summary

This one blinded randomized controlled trial is planned to investigate the effect of intravenous propofol versus sodium valproate on acute migraine headache in patients who refer to emergency ward of Farshchian hospital. After signing informed consent, the eligible patients will be assigned randomly into two different groups, propofol (P) versus sodium valproate (V). The P group will receive a single dose of 200 mg propofol mixed with 500 ml normal saline within 45 minute. The V group will receive 500 mg sodium valproate mixed with 500 ml normal saline within 45 minute. Severity of pain assists with Numerical Rating Scale (NRS) before administration of drugs and each 15 min during drug infusion and each 30 min for two hours. Also, in patient with reduced severity of pain we will assist pain severity for next 24 and 48 hours through the telephone.

General information

Acronym

ASA: American Society of Anesthesiologists; NRS: Numerical Rating scale

IRCT registration information

IRCT registration number: **IRCT2012121911822N1**
Registration date: **2013-04-04, 1392/01/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-04, 1392/01/15

Registrant information

Name

Behrooz Karkhanei

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0574

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of Research and Technology, Hamadan University of Medical Science

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous infusion of propofol and sodium valproate on alleviation of acute migraine

Public title

Comparison of intravenous infusion of propofol and sodium valproate on alleviation of acute migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Acute migraine attack; 20 to 50 years; ASA≤II
Exclusion criteria: Patient refuse; Allergy to propofol or sodium valproate; Allergy to egg or soya

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

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**

Local Human Subject Review Board

Street address

Hamadan University Of Medical Sciences, Shaheed
Famideh Street

City

Hamadan

Postal code

6517838695

Approval date

2013-02-24, 1391/12/06

Ethics committee reference number

D/P/16/35/9/4165

Health conditions studied**1****Description of health condition studied**

Migraine Headache

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

Headache severity

Timepoint

Before administration of drugs and each 15 min during
drug infusion and each 30 min for two hours. Also, in
patient with reduced severity of pain we will assist pain

severity for next 24 and 48 hours.

Method of measurement

Numerical Rating Scale (NRS), 0 for without pain and 10
for worst pain

Secondary outcomes**1****Description**

Any side effect such as allergy

Timepoint

Each 15 min during drug infusion and each 30 min for
two hours. Also, in patient with reduced pain for next 24
and 48 hours through the telephone.

Method of measurement

Ask from patient according to Questionnaire

Intervention groups**1****Description**

A single dose of 200 mg propofol mixed with 500 ml
normal saline within 45 minute.

Category

Treatment - Drugs

2**Description**

A single dose 500 mg sodium valproate mixed with 500
ml normal saline within 45 minute.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farshchian Hospital

Full name of responsible person

Shahir Mazaheri

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

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

Vice chancellor of Research and Technology,
Hamadan University of Medical Science

Full name of responsible person

Ahmad Tavilani

Street address

Vice chancellor of Research and Technology,
Hamadan University of Medical Sciences, Shaheed
Fahmideh Street

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of Research and Technology, Hamadan
University of Medical Science

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

Hamadan University of Medical Sciences

Full name of responsible person

Behrooz Karkhanei

Position

MD. Assistant Professor of Anesthesiology

Other areas of specialty/work

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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