Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 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

Email address

karkhanei@umsha.ac.ir

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

Street address

Medicine Faculty, Hamadan University of Medical Sciences, Shaheed Fahmideh

City

Hamadan

Postal code

Phone

+98 81 1838 0574

Fax

Email

karkhanei@umsha.ac.ir

Web page address

Person responsible for scientific 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

Street address

Medicine Faculty, Hamadan University of Medical Sciences, Shaheed Fahmideh

City

Hamadan

Postal code

Phone

+98 81 1838 0574

Fax

Email

karkhanei@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Zohreh Kheradmand

Position

Medical student

Other areas of specialty/work

Street address

Medicine Faculty, Hamadan University of Medical Sciences, Shaheed Fahmideh Street

City

Hamadan

Postal code

Phone

Fax

Email

kheradmand.zohreh@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