Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the therapeutic effects of dexamethasone, metoclopramide, ketorolac, and chlorpromazine on clinical symptoms of patients with acute migraine headache: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the therapeutic effects of dexamethasone, metoclopramide, ketorolac, and chlorpromazine on clinical symptoms of patients with acute migraine headache. Design: a double blind randomized clinical trial. Setting and conduct: The eligible patients with acute migraine headache who will refer to Sina Hospital during the study period will be enrolled into the trial. Inclusion criteria: Acute migraine headache; severity of pain at least 4 based on Visual Analog Scale. Exclusion criteria: Pregnancy; breastfeeding; hypertension; renal failure; heart disease; respiratory disease; liver failure; seizure; malignancy; infection or inflammation; peptic ulcer; neurological abnormalities; using immunosuppressive drugs; using ergotamine during last 8 hours; using sedative during last 4 hours. Intervention group: (a) metoclopramide 10 mg intravenous infusion during 15 min single dose; (b) dexamethasone 8 mg intravenous infusion during 15 min single dose; (c) ketorolac 30 mg intravenous infusion during 15 min single dose; (d) chlorpromazine 25 mg intravenous infusion during 15 min single dose Primary outcome: severity of headache before intervention and one and 24 hours after intervention using VAS. Secondary outcome: adverse effect of the drugs one and 24 hours after intervention through history taking. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611239014N133**
Registration date: **2016-11-28, 1395/09/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-11-28, 1395/09/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2006-02-20, 1384/12/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the therapeutic effects of dexamethasone, metoclopramide, ketorolac, and chlorpromazine on clinical symptoms of patients with acute migraine headache: a double blind randomized clinical trial

Public title
Comparison of the therapeutic effects of dexamethasone, metoclopramide, ketorolac, and chlorpromazine on clinical symptoms of patients with acute migraine headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Acute migraine headache; severity of pain at least 4 based on Visual Analog Scale. Exclusion criteria: Pregnancy; breastfeeding; hypertension; renal failure; heart disease; respiratory disease; liver failure; seizure; malignancy; infection or inflammation; peptic ulcer; neurological abnormalities; using immunosuppressive drugs; using ergotamine during last 8 hours; using sedative during last 4 hours.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2016-02-13, 1394/11/24
Ethics committee reference number
IR.UMSHA.REC.1394.641

Health conditions studied

1

Description of health condition studied
acute migraine headache
ICD-10 code
G43.1
ICD-10 code description
Migraine with aura

Primary outcomes

1

Description
severity of headache
Timepoint
before intervention and one and 24 hours after intervention
Method of measurement
using VAS

Secondary outcomes

1

Description
adverse effect of the drugs
Timepoint
one and 24 hours after intervention
Method of measurement
through history taking

Intervention groups

1

Description
Intervention group 1: metoclopramide 10 mg intravenous

infusion during 15 min single dose

Category

Treatment - Drugs

2

Description

Intervention group 2: dexamethasone 8 mg intravenous infusion during 15 min single dose

Category

Treatment - Drugs

3

Description

Intervention group 3: ketorolac 30 mg intravenous infusion during 15 min single dose

Category

Treatment - Drugs

4

Description

Intervention group 4: chlorpromazine 25 mg intravenous infusion during 15 min single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Nahid Hoseini Nejad Mir

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan 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

Sina Hospital

Full name of responsible person

Dr Nahid Hoseini Nejad Mir

Position

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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Position
Associate Professor

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