

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effect of ketorolac, morphine, and apotel in patients with head trauma: a double-blind randomized clinical trial

Protocol summary

Study aim

To compare the effect of the effect of ketorolac, morphine, and apotel in patients with head trauma

Design

A double blind randomized clinical trial

Settings and conduct

The eligible patients with head trauma who will refer to Besat Hospital of hamadan City during the study period will be enrolled into the trial and will be randomly assigned to the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: (a) head trauma during 24 hours; (b) age of 15 to 50 years; (c) severity of a headache equal to or greater than 4 based on VAS. Exclusion criteria: (a) decreased consciousness; (b) abnormal neurologic findings; (c) hemorrhagic and pathologic findings in brain CT scan; (d) history of hemorrhagic disorders or using anti-coagulant agents; (e) history of chronic headaches; (f) multiple trauma; (g) asthma; (h) addiction; (i) pregnancy; (j) renal failure, liver disease, cardiovascular diseases, pulmonary diseases

Intervention groups

Intervention group 1: Single dose infusion of apotel 15 mg/kg in 100 ml normal saline during 15 min.
Intervention group 2: Single dose infusion of ketorolac 30 mg in 100 ml normal saline during 15 min. Control group: Single dose infusion of morphine 0.1 mg in 100 ml normal saline during 15 min.

Main outcome variables

Primary outcome: Measuring the severity of a headache before, and 15 and 30 and 60 min after intervention using a visual analog scale (VAS). Secondary outcome: Assessing probable drug side effects (such as nausea, vomiting, dizziness, itching) by question 15 and 30 and 60 min after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201603089014N94**
Registration date: **2016-03-27, 1395/01/08**
Registration timing: **prospective**

Last update: **2018-12-10, 1397/09/19**

Update count: **1**

Registration date

2016-03-27, 1395/01/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ketorolac, morphine, and apotel in patients with head trauma: a double-blind randomized clinical trial

Public title

Comparison of the effect of ketorolac, morphine, and apotel in patients with head trauma

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age of 15 to 50 years; head trauma during 24 hours severity of headache equal to or greater than 4 based on VAS

Exclusion criteria:

Decreased consciousness
Abnormal neurologic findings
Hemorrhagic and pathologic findings in brain CT scan
A history of hemorrhagic disorders or using anti-coagulant agents
A history of chronic headaches
Multiple trauma
Asthma
Addiction
Pregnancy
Renal failure, liver disease, cardiovascular diseases, pulmonary diseases

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications will be prepared the same. Therefore, 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

Placebo

Not used

Assignment

Parallel

Other design features

.

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

Province

Hamadan

Postal code

6517838695

Approval date

2016-02-27, 1394/12/08

Ethics committee reference number

IR.UMSHA.REC.1394.498

Health conditions studied

1

Description of health condition studied

Head trauma

ICD-10 code

S09

ICD-10 code description

Other and unspecified injuries of head

Primary outcomes

1

Description

Measuring the severity of headache

Timepoint

before, and 15 and 30 min after intervention

Method of measurement

using visual analog scale (VAS)

Secondary outcomes

1

Description

Assessing probable drug side effects (such as nausea, vomiting, dizziness, itching)

Timepoint

15 and 30 min after intervention

Method of measurement

by question

Intervention groups

1

Description

Single dose infusion of apotel 15 mg/kg in 100 ml normal saline during 15 min

Category

Treatment - Drugs

2

Description

Single dose infusion of ketorolac 30 mg/kg in 100 ml normal saline during 15 min

Category

Treatment - Drugs

3

Description

Single dose infusion of morphine 1 mg/kg in 100 ml normal saline during 15 min

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Alireza Azimi Far

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

info.research@umsha.ac.ir

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

info.research@umsha.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Besat Hospital

Full name of responsible person

Dr Alireza Azimi Far

Position

Resident of Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Fax

Email

azimi_a1122@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Besat Hospital
Full name of responsible person
Dr Rasoul Salimi
Position
Emergency Medicine Specialist
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Fax
Email
rasoulsi@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available