Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
]nclusion criteria: (a) head trauma during 24 hours; (b) age of 15to 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; (i) 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

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Name of organization / entity
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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
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

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Hamadan

Province
Hamadan

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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