Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison between the effect of pethidine, ketorolac and ketorolac-diazepam combination in reducing pain in patients with acute low back pain referred to the emergency department

Protocol summary

Study aim

Comparison between pethidine, ketorolac and ketorolac-diazepam combination in reducing pain in patients with low back pain referred to Peymaniyeh hospital emergency department.

Design

The present study is a clinical trial with parallel, double-blind and randomized groups. The study population consisted of 90 patients admitted to the emergency room because of back pain patient is Peymanieh. Dice were used for randomization.

Settings and conduct

Written consent was obtained from all individuals and this study was approved by the Ethics Committee. In this double-blind randomized clinical trial, 90 patients who referred to the emergency department of Peymanieh Hospital in Jahrom due to acute low back pain were included in the study. Sampling was easy and patients were randomly divided into 3 groups of 30 by throwing dice.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with acute lumbar pain referred to the emergency department of Peymanieh Hospital in Jahrom in 2020. No entry conditions: Patients over 80 years of age and lack of conscious consent to participate in the study

Intervention groups

The first group is patients who received 50 mg of pethidine (IV), the second group received 30 mg of ketorolac (ampoule) and 10 mg of diazepam intravenously, and the third group received ketorolac alone 30 mg of ketorolac (ampoule).

Main outcome variables

In this study, pain was the main outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201003048903N1**
Registration date: **2020-10-21, 1399/07/30**
Registration timing: **retrospective**

Last update: **2020-10-21, 1399/07/30**
Update count: **0**

Registration date

2020-10-21, 1399/07/30

Registrant information

Name

Esmaeal Rayat Dost

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 5433 6085

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-25, 1398/08/03

Expected recruitment end date

2020-06-25, 1399/04/05

Actual recruitment start date

2019-11-27, 1398/09/06

Actual recruitment end date

2020-06-30, 1399/04/10

Trial completion date

2020-10-27, 1399/08/06

Scientific title
Comparison between the effect of pethidine, ketorolac and ketorolac-diazepam combination in reducing pain in patients with acute low back pain referred to the emergency department

Public title
The effect of pethidine, ketrolac and the combination of ketorolac and diazepam on low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who refer to the emergency department of Peymanieh Hospital in Jahrom due to acute low back pain in 2019-2020. Informed consent to attend the study

Exclusion criteria:

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In our study, patients were divided into 3 equal groups by block randomization. The randomization method was that for each group, 15 numbers in one envelope for men and 15 numbers in other envelopes for women were sampled by the nurse in charge (a total of 30 envelopes for each group). The nurse in charge of sampling for randomly referred patients once removed a number from a group of men and once a bag of women, respectively, and delivered it to the patient, to be delivered to the doctor by the time of referral. For the next group, the same thing was done consecutively with the first group, and for the third group, the same thing was repeated. The nurse wrote down in a notebook which group the person referred to the doctor belonged to and wrote it down. But neither the doctor nor the patient himself knew in which study group the patient was placed.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, physicians and nurses in the emergency department of Peymaniyeh Hospital, as well as those responsible for data collection, were blinded like patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Jahrom University of Medical Sciences

Street address
Jahrom University of Medical Sciences Campus Building ,Ostad Motahhari Blvd, after the School of Nursing and Midwifery, Jahrom City, Iran

City
Jahrom

Province
Fars

Postal code
7414846199

Approval date
2019-01-30, 1397/11/10

Ethics committee reference number
IR.JUMS.REC.1397.150

Health conditions studied

1

Description of health condition studied
low back pain

ICD-10 code
G89.29

ICD-10 code description
Other chronic pain

Primary outcomes

1

Description
Pain

Timepoint
In this study, the effect of pethidine, ketrolac and ketrolac-diazepam combination on patients' pain was measured in the time periods before injection, immediately after injection, 5, 10, 20, 60 and 90 minutes after injection.

Method of measurement
Pain variable was measured in this study using Visual Analogue Scale.

2

Description
blood pressure

Timepoint
In this study, the effect of pethidine, ketrolac and

ketrolac-diazepam combination on patients' blood pressure was measured in the time periods before injection, immediately after injection, 5, 10, 20, 60 and 90 minutes after injection.

Method of measurement

In this study, blood pressure was measured using a manual blood pressure monitor and a cuff monitoring device.

3

Description

Heart rate per minute

Timepoint

In this study, the effect of pethidine, ketrolac and ketrolac-diazepam combination on patients' heart rate was measured at the time before injection, immediately after injection, 5, 10, 20, 60 and 90 minutes after injection.

Method of measurement

The heart rate of patients in this study was measured by a nurse in the emergency department and a monitor installed in the emergency department.

4

Description

The amount of oxygen saturation in the blood

Timepoint

In this study, the effect of pethidine, ketrolac and ketrolac-diazepam combination on patients' blood oxygen saturation was measured at the time before injection, immediately after injection, 5, 10, 20, 60 and 90 minutes after injection. .

Method of measurement

Patients' blood oxygen levels were measured using a monitor installed in the emergency department.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group consisted of 30 patients with low back pain who received 50 mg of pethidine (intravenously).

Category

Treatment - Drugs

2

Description

Intervention group: The second group consisted of 30 patients with low back pain who received 30 mg of ketorolac (ampoule) and 10 mg of diazepam intravenously.

Category

Treatment - Drugs

3

Description

Intervention group: The third group consisted of 30 patients with low back pain who received 30 mg of ketrolac alone (ampoule) intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Peymaniyeh Hospital in Jahrom

Full name of responsible person

Dr Esmaeal Rayat Dost

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Jahrom 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Patients 'personal data, including patients' first and last names, will not be disclosed in accordance with ethical obligations. Data on the main outcomes of the study will be published.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Post-publication study data is available to all

researchers.

Under which criteria data/document could be used

The data can be used with the permission of the researcher and therapeutic uses.

From where data/document is obtainable

Research Council of Jahrom University of Medical Sciences

What processes are involved for a request to access data/document

Request for access to the data of the present study must be submitted in writing to the Committee and Research Council of Jahrom University of Medical Sciences and with ethical commitments.

Comments