Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of magnesium sulfate with ketorolac and morphine with ketorolac on pain in patients with colic

Protocol summary

Study aim

The effect of magnesium sulfate with ketorolac compared to morphine with ketorolac on reducing pain in patients with renal colic at 20, 40 and 60 minutes after drug administration

Design

This randomized, double-blind trial is conducted on 70 patients with renal colic. Patients will be randomly assigned to 35 populated groups

Settings and conduct

This study will be performed in the emergency department of Al-Zahra Hospital. 70 patients with colic will be selected by simple random sampling. Then they will be divided into two groups by computer randomization. Patients in the first group will receive magnesium sulfate with ketorolac and patients in the second group will receive morphine with ketorolac. The drugs will be prepared before the intervention and will be placed in syringes of the same shape and coded with labels a and b. Therefore, the researcher and the patient will not know the type of drug.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: patients with acute renal colic over the age of 16 years and consent to participate in the study. exclusion criteria: morphine or ketorolac susceptibility, renal dysfunction, injection of analgesic in the past 6 hours bleeding diseases, warfarin use, drug addiction, and Pregnancy and breastfeeding

Intervention groups

Magnesium Sulfate with ketorolac Group: Patients with renal colic in this group will be received magnesium sulfate with a dose of 30 mg/kg and ketorolac 30 mg intravenously. Morphine with ketorolac Group: Patients with renal colic in this group will be received morphine with a dose of 5mg and ketorolac 30 mg intravenously.

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160130026253N4**
Registration date: **2020-05-20, 1399/02/31**
Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**
Update count: **0**

Registration date

2020-05-20, 1399/02/31

Registrant information

Name
Alireza Abootalebi Ghahnavieh
Name of organization / entity
Isfahan University of medical sciences, Emergency Department, Isfahan, I. R, Iran.
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of magnesium sulfate with ketorolac and morphine with ketorolac on pain in patients with colic

Public title
The effect of magnesium sulfate with ketorolac and morphine with ketorolac on relief pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of renal colic Satisfaction of patients or their companions to enter the study
Exclusion criteria:
Allergy to morphine or ketorolac Renal dysfunction injection of analgesic in the past 60 hours bleeding diseases Use of warfarin Drug addiction Pregnancy and breastfeeding
Age
From **17 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
All patients will be randomly assigned to two intervention groups using the computer randomization method based on the sequence of numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Prescribing medication and recording the patient's pain score will be performed by a resident who is unaware of the type of medication and the patients will be unaware of the type of medication prescribed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib Ave, Azadi Square.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-03-09, 1398/12/19
Ethics committee reference number
IR.MUI.MED.REC.1398.665

Health conditions studied

1

Description of health condition studied
Renal colic
ICD-10 code
N23
ICD-10 code description
Renal colic

Primary outcomes

1

Description
Pain Score
Timepoint
20, 40, 60 minutes after drug administration
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Side effects
Timepoint
60 minutes after drug administration
Method of measurement
Observation

Intervention groups

1

Description
Patients with renal colic in this group will be received magnesium sulfate at a dose of 30 mg/kg and ketorolac at a dose of 30 mg in a volume of 100 cc at 15 minutes.
Category
Treatment - Drugs

2

Description
Intervention group: Patients with renal colic in this group

will be received morphine at a dose of 5mg and ketorolac at a dose of 30 mg in a volume of 100 cc at 15 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Al-Zahra Hospital

Full name of responsible person

Alireza Abootalebi

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Department of emergency medicine, Al-Zahra hospital, Soffeh Boulevard, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan Mortazavi

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Abootalebi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
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
Information about the main outcome can be shared.

When the data will become available and for how long
Start the access period 6 months after publishing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Use data to complete clinical trial studies

From where data/document is obtainable
A_abootalebi@yahoo.com

What processes are involved for a request to access data/document
After the investigation of researcher request and presentation of required documents will be accessible.

Comments