

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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.

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2085

Email address

a_abootalebi@med.mui.ac.ir

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

Isfahan

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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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