Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effect of intravenous ketorolac-morphine with intravenous ketorolac-magnesium sulfate on reducing pain in renal colic patients.

Protocol summary

Study aim

Comparison of the effect of intravenous magnesium sulfate with morphine in reducing the pain of acute renal colic patients in 20 minutes ,40 minutes,60 minutes. Comparison of the effect of intravenous magnesium sulfate with morphine in causing side effects in patients with acute renal colic.

Design

The patients and the pain intensity scorer will be blind to the study, so that the drugs of the control and intervention groups will be prepared before the start of the intervention and will be placed in syringes of the same shape and named with A and B codes. become Medicines are prescribed to the patient by the nurse, and the researcher measures the patient's pain score according to the VAS scale at different hours, while being unaware of the type of medicine prescribed to the patient.

Settings and conduct

In Ganjovian Hospital, Dezful

Participants/Inclusion and exclusion criteria

Patients older than 16 years with unilateral flank or hypogastric pain, any history of opium addiction, cardiac or renal failure, respiratory rate less than 12 per minute, systolic blood pressure less than 100 mmHg, unwillingness to participate in the study , sensitivity to ketorolac and morphine or magnesium sulfate, inability to understand the concept of VAS, use of painkillers 4 hours before admission, pregnancy and breastfeeding

Intervention groups

The first group (92 people): intravenous infusion of 0.1 mg/kg of morphine sulfate (maximum 5 mg) and 30 mg of ketorolac in 100 cc of normal saline for 15 minutes
The second group (92 people): intravenous infusion of 50 mg/kg (maximum 2 g) of magnesium sulfate and 30 mg of ketorolac in 100 cc of normal saline for 15 minutes

Main outcome variables

Reduction of pain by three points or more on the VAS scale after drug injection, which shows the effectiveness of the drug.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221219056870N1**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

Faezeh Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3372 7617

Email address

alighasemlou1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-07, 1401/10/17

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of intravenous ketorolac-morphine with intravenous ketorolac-magnesium sulfate on reducing pain in renal colic patients.

Public title
Investigating the effect of magnesum sulfate in reducing the pain of kidney stones
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 16 years Patients with flank or hypogastric pain Patients who have ultrasound based on kidney stones.
Exclusion criteria:
Known hypersensitivity to ketorolac and morphine or magnesium sulfate Pregnancy and breastfeeding Any history of opium addiction Breathing rate less than 12 per minute Systolic blood pressure less than 100 mm Hg Unwillingness to participate in the study Inability to understand the concept of VAS Heart or kidney failure Use of painkillers 4 hours before admission
Age
From **16 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **184**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are divided into two groups, the first group receives ketorolac and morphine, and the second group receives ketorolac and magnesium sulfate. The drugs are named in uniform syringes with codes A and B and administered to the patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients and the pain intensity scorer will be blind to the study, so that the drugs of the control and intervention groups will be prepared before the start of the intervention and will be placed in syringes of the same shape and named with A and B codes. become Medicines are prescribed to the patient by the nurse, and the researcher measures the patient's pain score according to the VAS scale at different hours, while being unaware of the type of medicine prescribed to the patient. More about this source textSource text required for additional translation information Send feedback Side panels
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Dezful University of Medical Sciences
Street address
azadegan
City
Dezful
Province
Khouzestan
Postal code
5841615797
Approval date
2022-11-01, 1401/08/10
Ethics committee reference number
IR.DUMS.REC.1401.071

Health conditions studied

1

Description of health condition studied
Acute renal colic
ICD-10 code
N20.0
ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Pain reduction of 3 points or more on the VAS scale after drug injection is considered positive.
Timepoint
20, 40 and 60 minutes
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The acute renal colic patients of this group are prescribed magnesium sulfate with a dose of 2 grams of a 50% solution in a volume of 100cc and at a speed of 15 minutes.
Category
Treatment - Drugs

2

Description
Control group: The acute renal colic patients of this group are prescribed morphine at a dose of 0.1 mg/kg in a volume of 100 cc and at a rate of 15 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ganjovian Dezful Hospital
Full name of responsible person
Mahdi Fallah Baqer Shidai
Street address
AZADEGAN
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dezfoul University of Medical Sciences
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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
Dezfoul University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Dezfoul University of Medical Sciences
Full name of responsible person
Mehdi Fallah Bagher SHeidaei
Position
Assistant Professor
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
No - There is not 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