Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effect of magnesium sulfate on the intensity and duration of pain in renal colic patients by a double-blind clinical trial in the case and control groups

Protocol summary

Study aim

Considering drug shortages and the prevalence of narcotic drugs in pain relief, this study is designed to reduce the need for narcotic drugs and define new drug combinations to relieve the pain of renal colic patients.

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 160 patients, to randomize an emergency medicine specialist.

Settings and conduct

This double-blind randomized clinical trial was designed to investigate the effect of intravenous magnesium sulfate in relieving pain in patients referred to the emergency department of Imam Khomeini Hospital (ED) following renal colic. Before entering the study, all patients will be given appropriate explanations about the study and sign the informed consent to enter the study, they are free to refuse to participate in the study and withdraw from the study. The place of research is Imam Khomeini Hospital in Ahvaz.

Participants/Inclusion and exclusion criteria

The inclusion criteria for this study are: clinical diagnosis of renal colic, age between 18 and 55 years, and pain intensity > 5 based on visual analog scale (VAS). Exclusion criteria were as follows: history of seizures. any heart, liver, kidney or metabolic disease; Fever (oral temperature > 38°C), systolic blood pressure less than 90 mmHg, pregnancy, acute abdomen, use of pargoric drug 3 hours before going to the emergency room, history of drug addiction or allergy and use of calcium channel blockers, recent gastrointestinal bleeding, Active peptic ulcer or recent perforation

Intervention groups

30 mg of ketorolac plus 15 mg/kg of 50% magnesium sulfate in 500 ml of normal saline is injected in 15 minutes.

Main outcome variables

Systolic blood pressure at 0, 30 and 60 minutes Diastolic blood pressure at 0, 30 and 60 minutes Pain intensity at 0, 30 and 60 minutes Pulse rate at 0, 30 and 60 minutes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230726058930N2**
Registration date: **2023-11-18, 1402/08/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-18, 1402/08/27**
Update count: **0**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name

Ali Vefagh Nematollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3367 5436

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of magnesium sulfate on the intensity and duration of pain in renal colic patients by a double-blind clinical trial in the case and control groups

Public title
Evaluation of the effect of magnesium sulfate in renal colic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of renal colic Age between 18 and 55 years Having a pain intensity > 5 based on the analog vision scale (VAS)
Exclusion criteria:
History of seizures Any heart, liver, kidney or metabolic disease Fever (oral temperature > 38 degrees Celsius) Systolic blood pressure less than 90 mm Hg pregnancy acute abdomen Taking pargoric medicine 3 hours before going to the emergency room History of drug addiction or allergy Taking calcium channel blockers Recent gastrointestinal bleeding, active peptic ulcer or recent perforation
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two groups using the balanced block randomization technique. For this purpose, blocks of four are prepared, the name of the witness is written on two sheets and the interventionist's name is written on the other two sheets. The sheets are piled up and placed in the container, and one sheet is pulled out for each patient without placing it. Then four sheets are returned to the container and this process is repeated until the sample volume is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The student researcher conducting the research who is responsible for data collection and the patients participating in this research were kept blinded. The emergency doctor and nurses know the difference between the control group and the intervention group. Patients will be adequately explained about the trial and will be excluded from the study if they do not wish to participate. After the patient's discharge, the research student will be informed about the medicine received by the patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committees of Ahbaz Jundishapur University of Medical Sciences
Street address
No. 385, Oribehesht St. Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135833843
Approval date
2023-08-26, 1402/06/04
Ethics committee reference number
IR.AJUMS.REC.1402.315

Health conditions studied

1

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

Primary outcomes

1

Description
intensity of pain
Timepoint
0, 30 and 60 minutes after starting the drug
Method of measurement
Visual Analogue Scale

2

Description
Systolic blood pressure
Timepoint

0, 30 and 60 minutes after starting the drug
Method of measurement
Electronic sphygmomanometer

3

Description
diastolic blood pressure
Timepoint
0, 30 and 60 minutes after starting the drug
Method of measurement
Electronic sphygmomanometer

4

Description
age
Timepoint
upon arrival
Method of measurement
Based on the patient's date of birth

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A dose of 30 mg of Ketorolac from Abidi Company plus 15 mg/kg of 50% magnesium sulfate from Shahid Ghazi Pharmaceuticals Company in 500 ml of normal saline is injected in 15 minutes.
Category
Treatment - Drugs

2

Description
Control group: patients receive 30 mg Ketorolac from Abidi Company and 30 ml of normal saline as a placebo in 500 ml of normal saline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeyni Hospital
Full name of responsible person
Ali Vefagh Nematollahi
Street address
Imam Khomeini Medical Education Center Ahvaz- Azadegan St.- Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoush ZakerKish
Street address
Jundishapur Medial science University, Esfand St, Golestan
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6135715794
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itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Vefagh Nematollahi
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
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