

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation Of The Effect Of Intravenous Magnesium Sulfate On Pain Relief In Patients With Acute Renal Colic- A Randomized Double Blind Clinical Trial

Protocol summary

Study aim

- Comparison Of The Effect Of Intravenous Magnesium Sulfate With Morphine On Pain Reduction In Patients With Acute Renal Colic In 20 Minutes
- Comparison Of Effect Of Intravenous Magnesium Sulfate With Morphine On Pain Reduction In Patients With Acute Renal Colic In 30 Minutes
- Comparison Of Effect Of Intravenous Magnesium Sulfate With Morphine On Pain Reduction In Patients With Acute Renal Colic In 60 Minutes
- Comparison Of The Effect Of Intravenous Magnesium Sulfate With Morphine On Pain Reduction In Patients With Acute Renal Colic In 120 Minutes
- Comparison Of Effect Of Intravenous Magnesium Sulfate With Morphine On Pain Reduction In Patients With Acute Renal Colic In 180 Minutes
- Determining And Comparing The Effect Of Intravenous Magnesium Sulfate On Pain Reduction In Patients With Acute Renal Colic In Minutes 20, 30, 60, 120, And 180
- Determine And Compare The Effect Of Morphine On Pain Reduction In Patients With Acute Renal Colic In Minutes 20, 30, 60, 120 And 180
- Comparison Of The Effect Of Intravenous Magnesium Sulfate With Morphine On Adverse Reactions In Patients With Acute Renal Colic
- Comparison Of The Effect Of Intravenous Magnesium Sulfate With Morphine On Patients' Satisfaction With Acute Renal Colic

Design

Initially, Patients With Acute Renal Colic Who Were Eligible For Study And Received Morphine Treatment After 20 Minutes, Also Had A Score Of More Than 6, Were Taken To Participate In A Written And Informed Consent Study, And Then, According To A Random Number Table And Were Randomly Divided Into Two Equal Groups.

Settings and conduct

A Randomized, Double Blind Clinical Trial Study On Patients With Acute Renal Colic In An Adult Age Group Of 18-60 Years Old Referred To Shahid Beheshti University Of Medical Sciences Hospital In Shohadaye Tajrish

Affiliated To Shahid Beheshti University Of Medical Sciences During 2018.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The adult patients with acute renal colic, Age ranges of 18-60 years old, The severity of pain between 6 to 10 based on the vas criteria GCS= 15.
Exclusion Criteria: Pregnancy Or Suspicion Of Pregnancy, History Of Alcohol Addiction Sensitization To Morphine Or Pain Medication, History Of Mental Illness And Depression And Recent Sedation Or Antipsychotics And Calcium Intake Of Blocker Channel, History Of Drug Dependence, Receiving Analgesic In 6 Recent Illness, Neuromuscular Disease And Underlying Bradycardia (Heart Rate Less Than 60), Long Qrs Interval, History Of Heart And Kidney Disease, Liver And Liver Disease, Seizure And History Of Drop In Pressure, Abdominal Pain And Probability Of Peritonitis, Lack Of Consent Of The Patient From Continuing The Study, Unstable Patient With Clinical Condition And Pressure Drop (Systolic Pressure Less Than 90 Or Pressure Foot 20% Of The Base) And A Drop In Heart Rate To Less Than 8, And A Drop In Respiratory Rate To Less Than 60 During The Study.

Intervention groups

Magnesium Sulfate Group: Patients With Acute Renal Colic In This Group Received Magnesium Sulfate At A Dose Of 2 G Of 50% Solution At 100 Cc At 15 Minutes.
Morphine Group: In Patients With Acute Renal Colic, Morphine Was Administered At A Dose Of 0.1 Mg / Kg To 100 Cc At 15 Minutes.

Main outcome variables

The Primary Outcome Was Pain Reduction And Pain Score Of Less Than 3 Which Was Recorded At 0, 20, 30, 60, 120, 180 And 180 Minutes After Injection In Patients With Acute Renal Colic, Both Groups Of Morphine And Magnesium Sulfate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171206037774N1**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Fatemeh Derakhshani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2274 1429

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Of The Effect Of Intravenous Magnesium Sulfate On Pain Relief In Patients With Acute Renal Colic- A Randomized Double Blind Clinical Trial

Public title

The Effect Of Venous Magnesium Sulfate On Pain Relief In Patients With Acute Renal Colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The Adult Patients With Acute Renal Colic Are Between The Ages Of 18-60 And The Severity Of Pain Between 6 To 10 Based On The VAS Criteria And GCS= 15.

Exclusion criteria:

Pregnancy Or Suspicion Of Pregnancy, History Of Alcohol Addiction Sensitization To Morphine Or Pain Medication, History Of Mental Illness And Depression And Recent Sedation Or Antipsychotics And Calcium Intake Of Blocker Channel, History Of Drug Dependence, Receiving Analgesic In 6 Recent Illness, Neuromascular Disease And Underlying Bradycardia (Heart Rate Less Than 60), Long Qrs Interval, History Of Heart And Kidney Disease, Liver And Liver Disease, Seizure And History Of Drop In Pressure, Abdominal Pain And Probability Of Peritonitis,

Lack Of Consent Of The Patient From Continuing The Study, Unstable Patient With Clinical Condition And Pressure Drop (Systolic Pressure Less Than 90 Or Pressure Foot 20% Of The Base) And A Drop In Heart Rate To Less Than 8, And A Drop In Respiratory Rate To Less Than 60 During The Study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization Table Of Random Numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Due To The Double-Blindness Of The Study, Throughout The Study, The Patients, Physicians, Nurse-Injectors Were Unaware Of All Stages Of The Study, And The Preparation And Injection Of Medications By Two Nurses Or Residents Was Carried Out So That The Person Preparing The Medication From The Recipient The Medication And The Nurse Injecting Drug Was Unaware. All Drug Injection Syringes Were United And Randomized And Recorded By One Person (Emergency Medicine Assistant).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Chamran Highway (Evin), adjacent to Taleghani Hospital, Shahid Beheshti University of Medical Sciences, Building No. 2, 6th floor, Secretariat of the Ethics Committee, Research Directorate

City

Tehran

Province

Tehran

Postal code

1617181514

Approval date

2017-07-16, 1396/04/25

Ethics committee reference number

2548

Health conditions studied**1****Description of health condition studied**

Acute Renal Colic

ICD-10 code

N23

ICD-10 code description

Renal Colic

Primary outcomes**1****Description**

Reducing Pain

Timepoint

20, 30, 60, 120, 180 min

Method of measurement

VAS

Secondary outcomes**1****Description**

Side Effect

Timepoint

180 min

Method of measurement

Observation

Intervention groups**1****Description**

Intervention Group: Patients With Acute Renal Colic In This Group Received Magnesium Sulfate At A Dose Of 2 G Of 50% Solution At 100 Cc At 15 Minutesmagnesium sulfate at a dose of 2 g of 50% solution at 100 cc at 15 minutes.

Category

Treatment - Drugs

2**Description**

Control group: In Patients With Acute Renal Colic, Morphine Was Administered At A Dose Of 0.1 Mg / Kg To 100 Cc At 15 Minutes.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada Tajrish Hospital

Full name of responsible person

Alireza Majidi

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Tajrish Square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Shahid Beheshti 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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Full name of responsible person
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Associate Professor
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Person responsible for updating data

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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

Yes - There is 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

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

Title and more details about the data/document

All Collected Data Will Analyzed Then Will Accessible To All In The Form Of A Dissertation As Well As A Published Article.

When the data will become available and for how long

After Publishing the Paper.

To whom data/document is available

All Collected Data Will Analyzed Then Will Accessible To All In The Form Of A Dissertation As Well As A Published Article.

Under which criteria data/document could be used

All Collected Data Will Analyzed Then Will Accessible To All In The Form Of A Dissertation As Well As A Published Article.

From where data/document is obtainable

The Journal Website

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

Search in Databases

Comments