Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of Intravenous Lidocaine, Intravenous Magnesium Sulfate and Intravenous Ketorolac for Pain Management In Patient With Renal Colic

Protocol summary

Study aim

Comparison of the effectiveness of intravenous lidocaine, intravenous magnesium sulfate, and intravenous ketorolac in controlling pain in patients with renal colic.

Design

Phase 3 clinical trial with control and intervention groups with parallel groups, double-blind, randomized using a simple random number table on 100 patients

Settings and conduct

This study will be performed in the emergency department of Imam Reza Hospital in Tabriz, East Azerbaijan province. The patients were randomly divided into 3 groups, and in the control group, intravenous ketorolac, in the first intervention group, intravenous magnesium sulfate, and in the second intervention group, intravenous lidocaine will be administrated. Pain score before drug administration and 5, 10, 15 and 30 minutes after will be checked and recorded using the VAS tool. The patient and the outcome examiner will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

People between 18 and 65 years old with acute renal colic will be included in the study. Patients with a history of kidney failure, liver disease, heart disease, asthma, or a history of allergy to the drugs used in this study, and pregnant patients will not be included in the study.

Intervention groups

In the control group, 30 mg of ketorolac will be injected intravenously and 500 cc of normal saline will be prescribed as a placebo. In the magnesium sulfate group, 2 grams of magnesium sulfate in 500 cc of normal saline will be injected to the patient and 10 cc of normal saline will be prescribed as a placebo. In the lidocaine group, the amount of 1.5 mg of lidocaine per kilogram of body weight will be injected to the patient and 500 cc of normal saline will be prescribed as a placebo.

Main outcome variables

Pain score at 5, 10, 15 and 30 minutes after drug administration using VAS tool

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090923002496N13**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**
Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Hassan Soleimanpour

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1329 1286

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-01-05, 1402/10/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Intravenous Lidocaine, Intravenous Magnesium Sulfate and Intravenous Ketorolac for Pain Management In Patient With Renal Colic

Public title
Lidocaine and magnesium sulfate in renal colic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with acute renal colic
Exclusion criteria:
History of kidney disease History of cardiac disease History of hepatic disease Pregnant patients History of asthma History of allergy to any of the drugs in study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into three groups in a simple and individual way using a table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Study participants will be blinded to their group by using placebo. The examiner of the results will also be blinded to the category in which the patient is located.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethic committee of Research Vice chancellor of Tabriz University of Medical Sciences
Street address
Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN
City
Tabriz
Province
East Azarbaijan
Postal code
5166614776
Approval date
2023-03-06, 1401/12/15
Ethics committee reference number
IR.TBZMED.REC.1402.005

Health conditions studied

1

Description of health condition studied
Renal colic
ICD-10 code
N20-N23
ICD-10 code description
Urolithiasis

Primary outcomes

1

Description
Pain score in 5th, 10th, 15th and 30th minutes after drug administration
Timepoint
5, 10, 15, 30 minutes
Method of measurement
VAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: intravenous Lidocaine
Category
Treatment - Drugs

2

Description
Intervention group: intravenous magnesium sulfate
Category
Treatment - Drugs

3

Description
Control group: intravenous ketorolac

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Dr.Hassan Soleimanpour
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Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
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Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Hassan Soleimanpour
Position
Professor of Anesthesiology
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

Hassan Soleimanpour

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

Yes - There is 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 individual data from the study will be accessible after de-identification.

When the data will become available and for how long

2024

To whom data/document is available

Data will be available for all interested researchers

Under which criteria data/document could be used

Data will be available for use in other studies. researchers can ask for data of this study by sending email to dr. Hassan Soleimanpour

From where data/document is obtainable

Dr. Hassan Soleinampour soleimanpourh@tbzmed.ac.ir

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

By sending an e-mail request, the documents can be received within a period of about two weeks.

Comments