

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 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

soleimanpourh@tbzmed.ac.ir

##### 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

**Street address**

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.

**City**

Tabriz

**Province**

East Azarbaijan

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5166614756

**Phone**

+98 41 3335 2078

**Email**

soleimanpourh@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Parviz Shahabi

**Street address**

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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shahabip@tbzmed.ac.ir

**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**

Anesthesiology

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hassan Soleimanpour

**Position**

professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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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