

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of intravenous magnesium sulfate and intravenous ketorolac on pain of patients with renal colic

#### Protocol summary

##### Summary

Objective: Comparison the effect of intravenous magnesium sulfate and intravenous ketorolac on pain of patients with renal colic Design: Parallel single blind randomized clinical trial Randomization: Patients will allocate to two equal groups according to table of random numbers. Participants including major eligibility criteria: This study will conduct on 84 patients with renal colic affiliated to acute emergency department of Ahvaz Golestan hospital. Main inclusion criteria include diagnosis of renal colic with sonography; age of 18-55 years; having pain score of 5 based on visual analog score in admission time and main exclusion criteria include having history of heart, liver, kidney, metabolic diseases and seizures; systolic blood pressure below 90 mmHg; fever more than 37 degrees Celsius; pregnancy; abdominal pain and probable peritonitis; using calcium channel blockers. Main outcome: Pain severity Intervention: Patients in first group will receive ketorolac via intravenous with dosage of 30 mg in combination to 100 cc intravenous normal saline during 15 minutes. Patients in second group will receive 50 mg per kilogram intravenous magnesium sulfate 50% with total dosage of 100 cc during 15 minutes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016050125027N2**  
Registration date: **2016-12-21, 1395/10/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-21, 1395/10/01

#### Registrant information

##### Name

Mohammadreza Maleki Varaki

##### Name of organization / entity

Ahvaz Judishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3079

##### Email address

maleki-m@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Ahvaz Judishapur University of Medical Sciences

#### Expected recruitment start date

2016-12-20, 1395/09/30

#### Expected recruitment end date

2017-03-10, 1395/12/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the effect of intravenous magnesium sulfate and intravenous ketorolac on pain of patients with renal colic

#### Public title

Comparison the effect of intravenous magnesium sulfate and intravenous ketorolac on pain of patients with renal colic affiliated to acute emergency department of Ahvaz Golestan hospital

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of renal colic with sonography; age of 18-55 years; having pain score of 5 based on visual analog score in admission time.  
Exclusion criteria: history of heart, liver, kidney, metabolic diseases and seizures; systolic blood pressure below 90 mmHg; fever more than 37 degrees Celsius; pregnancy; abdominal pain and probable peritonitis; using calcium channel blockers.

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

**Street address**

Ahwaz Jundishapur University of Medical Sciences, Golestan road, Ahwaz, Khuzestan

**City**

Ahwaz

**Postal code****Approval date**

2016-10-29, 1395/08/08

**Ethics committee reference number**

IR.AJUMS.REC.1395.458

**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**

Pain severity

**Timepoint**

In 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Visual analog scale

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

Pulse rate

**Timepoint**

In 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Researcher-made questionnaire

**2****Description**

Blood pressure rate

**Timepoint**

In 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Researcher-made questionnaire

**3****Description**

Atrial oxygen saturation

**Timepoint**

In 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Researcher-made questionnaire

**4****Description**

Respiratory rate

**Timepoint**

In 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Researcher-made questionnaire

**5****Description**

Nausea and vomiting

**Timepoint**

In 15, 30, 45 and 60 minutes after intervention

**Method of measurement**

Researcher-made questionnaire

## Intervention groups

1

### Description

Patients in first group will receive ketorolac via intravenous with dosage of 30 mg in combination to 100 cc intravenous normal saline during 15 minutes

### Category

Treatment - Drugs

2

### Description

Patients in second group will receive 50 mg per kilogram intravenous magnesium sulfate 50% with total dosage of 100 cc during 15 minutes.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ahvaz Golestan hospital

#### Full name of responsible person

Mohammadreza Maleki Varaki

#### Street address

Golestan hospital, Golestan road, Ahvaz, Khuzestan

#### City

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice chancellor for research, Ahvaz Judishapur University of Medical Sciences

#### Full name of responsible person

Nader Saki

#### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

#### City

Ahvaz

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Vice chancellor for research, Ahvaz Judishapur University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Mohammadreza Maleki Varaki

#### Position

Emergency medicine specialist

#### Other areas of specialty/work

#### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

#### City

Ahvaz

#### Postal code

61357-15794

#### Phone

+98 61 3320 8342

#### Fax

#### Email

Maleki-m@ajums.ac.iradelaryan61@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Mohammadreza Maleki Varaki

#### Position

Emergency medicine specialist

#### Other areas of specialty/work

#### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

#### City

Ahvaz

#### Postal code

#### Phone

+98 61 3320 8342

#### Fax

#### Email

Maleki-m@ajums.ac.iradelaryan61@gmail.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Adel Arian

**Position**

Emergency medicine resident

**Other areas of specialty/work****Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Golestan road, Ahvaz, Khuzestan

**City**

Ahvaz

**Postal code****Phone**

00

**Fax****Email**

adelaryan61@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*