

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Efficacy of magnesium sulfate in treatment of acute renal colic

#### Protocol summary

##### Summary

In this double-blind clinical trial, 100 patients with a clinical diagnosis of acute renal colic and acute pain radiating to the groin or lower abdomen suddenly after obtaining informed consent based on inclusion criteria aged 18 to 55 years and more intense pain than 5 exclusion criteria a history of seizures, heart disease, liver, kidney or metabolic, systolic blood pressure less than 90 were enrolled. After obtaining demographic information and vital signs, ECG and arterial oxygen saturation are randomly assigned to one of two groups. The first group treated with the standard protocol of 0.1 mg per kg of morphine and 30 mg ketorolac with 100 ml of normal saline as placebo as a 15 minute intravenous infused. The second group, in addition to the standard protocol, 15 mg per kg of magnesium sulfate intravenously with 50% of the total volume 100 ml (dissolved in saline) will be administered within 15 minutes. The pain VAS score and vital signs and arterial oxygen saturation on admission and after 30 and 60 minutes after injection is measured. In the case of VAS higher than 5 in each group 30 minutes after the first dose of 3 mg of morphine in morphine consumption in patients will be recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020223552N6**

Registration date: **2016-04-23, 1395/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-23, 1395/02/04

##### Registrant information

Name

Abolfazl Jokar

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3313 2134

##### Email address

dr.a.jokar@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor Arak University of Medical Sciences

##### Expected recruitment start date

2014-11-22, 1393/09/01

##### Expected recruitment end date

2015-08-23, 1394/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of magnesium sulfate in treatment of acute renal colic

##### Public title

Efficacy of magnesium sulfate in treatment of acute renal colic

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Clinical diagnosis of renal colic; aged between 18 and 55 years; VAS > 5. Exclusion criteria: A history of seizures, heart, liver, kidney or metabolic disease; T > 38; systolic blood pressure < 90 mm Hg; pregnancy; abdominal pain; opioid addiction; use of calcium channel blocker.

##### 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: **100**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**  
randomization Will be done with using a random number table

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

St. Alamolhoda, St. Maskan, Arak

##### City

Arak

##### Postal code

#### Approval date

2015-06-08, 1394/03/18

#### Ethics committee reference number

IR.ARAKMU.REC.1394.44

## Health conditions studied

### 1

#### Description of health condition studied

acute renal colic

#### ICD-10 code

9

#### ICD-10 code description

N20,N21,N22,N23

## Primary outcomes

### 1

#### Description

Pain  
**Timepoint**  
Arrival, 30 minutes and 60 minutes after injection  
**Method of measurement**  
VAS ruler

## Secondary outcomes

### 1

#### Description

Arterial oxygen saturation

#### Timepoint

At Arrival and 30 minutes and 60 minutes after injection

#### Method of measurement

Digital pulse oxymetry

### 2

#### Description

Systolic Blood Pressure

#### Timepoint

At Arrival and 30 minutes and 60 minutes after injection

#### Method of measurement

sphingmomonometer

### 3

#### Description

Diastolic Blood Pressure

#### Timepoint

At Arrival and 30 minutes and 60 minutes after injection

#### Method of measurement

sphigmomonometer

### 4

#### Description

Heart Rate

#### Timepoint

At Arrival and 30 minutes and 60 minutes after injection

#### Method of measurement

Pulse per minute

### 5

#### Description

Respiratory Rate

#### Timepoint

At Arrival and 30 minutes and 60 minutes after injection

#### Method of measurement

Respiration Per Minute

## Intervention groups

### 1

#### Description

Intervention group: 15 mg/kg of magnesium sulfate 50 % ( institute Pasteur.Tehran .Iran )with total volume 100 ml (dissolved in Normal saline) will be administered intravenously within 15 minutes. in addition Treatment

with the standard protocol of 0.1 mg/kg of morphine sulfate and 30 mg ketorolac intravenously the same time

**Category**

Treatment - Drugs

**2****Description**

Control group : 100 ml of normal saline as placebo will be administered intravenously within 15 minute. in addition Treatment with the standard protocol of 0.1 mg/kg of morphine sulfate and 30 mg ketorolac intravenously the same time

**Category**

Treatment - Drugs

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

arak valiasr hospital

**Full name of responsible person**

ad abolfazl jokar

**Street address****City**

arak

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

Vice Chancellor for research of Arak University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Rafiee

**Street address**

School of Medicine, Arak

**City**

Arak

**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 of Arak 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**

Arak University of Medical sciences

**Full name of responsible person**

Dr. Abolfazl Jokar

**Position**

Emergency medicine specialist

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

Vali Asr Hospital, Arak

**City**

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**Postal code****Phone**

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**Fax****Email**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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

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**City**

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**Postal code****Phone**

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**Fax**

**Email**

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**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*