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 ketrolac 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 Sceinces

Country

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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 oxymetery

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 sceinces

Full name of responsible person

Dr. Abolfazl Jokar

Position

Emergency medicine specialist

Other areas of specialty/work

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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