

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison the analgesic efficacy of intramuscular morphine and morphine suppository in patients with renal colic

Protocol summary

Summary

The aim of this randomized controlled clinical trial is to compare the efficacy of intramuscular morphine and morphine suppository in relieving pain of patients with renal colic. The study will be done on 18 to 55 years old patients with renal colic who will come to the emergency department of Kowsar hospital in Semnan, Iran. Patients with unilateral acute flank or abdominal colicky pain will be included in the study that in evaluation of the patient with ultrasonography, CT scan or intravenous pyelography presence of the urinary stone will be approved or the patient will pass the stone. Exclusion criteria will be sensitivity to morphine, addiction, existence of fever, impaired hepatic or renal function, heart or respiratory failure, suspected to peritonitis, pregnancy and receiving analgesic within 6 hours before admission. Sample size will be 84 patients that will be divided with randomized permuted blocks into two groups (42 in each group). For control of pain one group will receive 10 mg intramuscular morphine and the other group 10 mg morphine suppository. First, the intensity of patient pain will be assessed based on VAS (visual analogue scale) and after control of blood pressure, pulse and respiratory rate and recording them in the questionnaire, they will be treated with morphine suppository or intramuscular morphine. In 15, 30 and 60 minutes intervals after drug prescription, reevaluation according to pain relief based on VAS as well as morphine side effects will be done. Demographic data, VAS points and drug side effects will be recorded in the questionnaire.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015111825098N1**

Registration date: **2016-03-18, 1394/12/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-18, 1394/12/28

Registrant information

Name

Arash Ardestani Zadeh

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7830

Email address

arardestani@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

university

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the analgesic efficacy of intramuscular morphine and morphine suppository in patients with renal colic

Public title

Comparison the analgesic efficacy of intramuscular morphine and morphine suppository in renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-55 years old patients with unilateral acute flank or abdominal colicky pain that in evaluation of the patient with ultrasonography, CT scan or intravenous pyelography presence of the urinary stone is approved or the patient passes the stone. Exclusion criteria : sensitivity to morphine; addiction; fever higher than 38 degrees of centigrade; unstable hemodynamic condition; impaired hepatic or renal function; heart failure; respiratory failure; suspected to peritonitis; pregnancy or suspected to pregnancy; transplanted kidney; suspected to aneurysm or dissection of aorta and receiving analgesic within 6 hours before admission.

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)

Not 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 Semnan University of Medical Sciences

Street address

Central building of the university, Basij Blvd., Semnan

City

Semnan

Postal code

Approval date

2016-01-05, 1394/10/15

Ethics committee reference number

IR SEMUMS.REC.1394.129

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 intensity

Timepoint

Before intervention, 15, 30 and 60 minutes after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before intervention, 15, 30 and 60 minutes after intervention

Method of measurement

Sphygmomanometer

2

Description

Heart rate

Timepoint

Before intervention, 15, 30 and 60 minutes after intervention

Method of measurement

Counting the number of radial pulse

3

Description

Respiratory rate

Timepoint

Before intervention, 15, 30 and 60 minutes after intervention

Method of measurement

Counting the number of breaths

4

Description

Nausea and Vomiting

Timepoint

Before intervention, 15, 30 and 60 minutes after intervention

Method of measurement

Question of the patient and observation

5**Description**

Dizziness

Timepoint

15, 30 and 60 minutes after intervention

Method of measurement

Question of the patient

6**Description**

Drowsiness

Timepoint

15, 30 and 60 minutes after intervention

Method of measurement

Observation

7**Description**

Facial Flushing

Timepoint

15, 30 and 60 minutes after intervention

Method of measurement

Observation

8**Description**

Size of urinary stone

Timepoint

After intervention

Method of measurement

Imaging findings

9**Description**

Location of the stone

Timepoint

After intervention

Method of measurement

Imaging findings

Intervention groups**1****Description**

Intervention group: Patients with renal colic that receive 10 mg intramuscular Morphine Sulfate (manufactured by Darou Pakhsh Pharmaceutical Co.) for control of pain

Category

Treatment - Drugs

2**Description**

Control group: Patients with renal colic that receive 10

mg suppository of Morphine Sulfate (brand name: Opirect, manufactured by Aburaihan Pharmaceutical Co.) for control of pain

Category

Treatment - Drugs

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

Kowsar hospital

Full name of responsible person

Dr Arash Ardestani Zadeh

Street address

Kowsar hospital, Basij Blvd., Semnan

City

Semnan

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

Vice Chancellor for research of Semnan University of Medical Sciences

Full name of responsible person

Dr Ali Rashidypour

Street address

Central building of university, Basij Blvd., Semnan

City

Semnan

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 Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Dr Arash Ardestani Zadeh

Position

Fellowship of Endourology

Other areas of specialty/work

Street address

Kowsar hospital, Basij Blvd., Semnan

City

Semnan

Postal code

3519899951

Phone

+98 23 3343 7830

Fax

+98 23 3343 7837

Email

ardestani_a@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Arash Ardestani Zadeh

Position

Fellowship of Endourology

Other areas of specialty/work

Street address

Kowsar hospital, Basij Blvd., Semnan

City

Semnan

Postal code

3519899951

Phone

+98 23 3343 7830

Fax

+98 23 3343 7837

Email

ardestani_a@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Dr Arash Ardestani Zadeh

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Street address

Kowsar hospital, Basij Blvd., Semnan

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Fax

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Email

ardestani_a@yahoo.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