

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparing the efficacy of intradermal sterile water injection and intravenous morphine to control pain in patients with renal colic

Protocol summary

Study aim

Comparing the efficacy of intradermal sterile water injection and intravenous morphine to control pain in patients with renal colic

Design

Two arm parallel group randomized trial and double blinded

Settings and conduct

The study done in Imam Khomein and Golestan hospital in ahvaz. Drugs were numbered and third person choose the program. The nurse who injected drugs, regarding the numeral of drugs, intervened. In sterile water group, intradermal sterile water and intravenous sterile water were received and in morphine group, intradermal normal saline and intravenous morphine injection received.

Participants/Inclusion and exclusion criteria

18 to 55 years old Secondary education or more History of nephrolithiasis which is documented in imaging study VAS score is 5 or more Volunteer Satisfaction Contraindications of morphine administration Pregnancy Lactation Trauma Neuropathic pain in patients with lower back pain Liver dysfunction Renal dysfunction History of cardiac arrhythmia Peritonitis or pyelonephritis GCS less than 15 Body weight more than 100 kilograms Analgesic administration, before 6 hours presenting in Emergency Department Drug addiction or receiving methadone Do not satisfaction in project presentation

Intervention groups

Patients with renal colic pain who come to Imam khomeini and Golestan Hospital of ahvaz and injection of intradermal sterile water and intravenous morphine

Main outcome variables

pain in sterile water and morphine group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181012041315N1**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Reza Mahjouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3843

Email address

mahjouri2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-03-20, 1397/12/29

Scientific title

Comparing the efficacy of intradermal sterile water injection and intravenous morphine to control pain in patients with renal colic

Public title

Comparing the efficacy of intradermal sterile water injection and intravenous morphine to control pain in patients with renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Secondary education or more History of nephrolithiasis which is documented in imaging study with renal colic VAS score is 5 or more Volunteer Satisfaction

Exclusion criteria:

Contraindication of morphine administration pregnancy Lactation Trauma Neuropathic pain in lower back Liver dysfunction Renal dysfunction History of cardiac arrhythmia Peritonitis or pyelonephritis GCS less than 15 Body weight more than 100 kilograms Administration of analgesics, 6 hours before presenting in Emergency Department Drug addiction or receiving Methadone Do not satisfaction in project presence

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **94**

Actual sample size reached: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with block sizes of 4

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient and the nurse who injected drugs were blinded. Drugs were numbered and injected regarding the numbers which is mounted in the drugs

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Ahvaz university of Medical Sciences

Street address

golestan

City

ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

IR.AJUMS.REC.1396.1135

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

Timepoint

before, 15 and 30 and 45 and 60 minutes after injection of drug

Method of measurement

10 cm Visual Analog Scale score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1: Sterile water group, 0.5 ml intradermal Sterile water in 49 patients in Sterile water group was injected, then 5 ml intravenous normal saline was injected, patients were observed one hour after injection.

Category

Treatment - Drugs

2

Description

Intervention group: 2: Morphine group, 1 ml/kg intravenous morphine in 49 patients in morphine group was injected, then 0.5 ml intradermal normal saline was injected, patients were observed one hour after injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini and Golestan hospital of ahvaz

Full name of responsible person

Reza Mahjouri

Street address

Golestan

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 11 3340 9544

Email

mahjouri2003@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Javad Mozaffari

Street address

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Province

Khuzestan

Postal code

6135715794

Phone

+98 11 3340 9544

Email

info@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Mahjouri

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Mahjouri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Total data will be shareable after unidentified.

When the data will become available and for how long

1399

To whom data/document is available

Researcher

Under which criteria data/document could be used

Traetment

From where data/document is obtainable

Dr. Javad Mozaffari

What processes are involved for a request to access data/document

Request from Emergency Department of Ahvaz university of medical scince

Comments