

# 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**

Khouzestan

**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**

Golestan

**City**

Ahvaz

**Province**

Khouzestan

**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

**Street address**

Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 11 3340 9544

**Email**

mahjouri2003@yahoo.com

## 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**

Emergency Medicine

**Street address**

Golestan

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**Email**

mahjouri2003@yahoo.com

## Person responsible for updating data

### 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

**Street address**

Golestan

**City**

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**Email**

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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**