

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative survey of nebulized morphine and intravenous morphine for decreasing renal colic patients' pain

Protocol summary

Study aim

Comparative survey of nebulized morphine and intravenous morphine for decreasing renal colic patients' pain.

Design

In this research, 50 patients with renal colic divided in two groups randomly. Emergency department nurse starts the treatment with IV and nebulized morphine.

Settings and conduct

Location: Shahid Sadoughi Hospital and Shahid Rahnemoun Hospital in Yazd. The patient, the nurse, the researcher, the result evaluator, data analyzer, aren't aware of treatment method.

Participants/Inclusion and exclusion criteria

All patient above 18 years old with renal colic who has severe pain that are confirmed by urine analysis or ultrasonography. exclusion criteria : Morphine sensitivity , systole blood pressure < 110 millimeter mercury - respiratory rate < 12 per minute - saturation of oxygen < 95 percent , rhinitis or nose blocking , using pain-killer in 6 hours before visit and people with asthma and morphine sensitivity don't get surveyed.

Intervention groups

In first group : 5 mg morphine iv + 5 cc n/s nebulize (placebo) and in second group 10 mg morphine nebulize + 5 cc n/s iv treated.

Main outcome variables

pain level , side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171226038089N1**

Registration date: **2018-02-18, 1396/11/29**

Registration timing: **retrospective**

Last update: **2018-02-18, 1396/11/29**

Update count: **0**

Registration date

2018-02-18, 1396/11/29

Registrant information

Name

Ali Saadat Yar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3821 5128

Email address

alisaadatyar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

2016-12-21, 1395/10/01

Actual recruitment end date

2017-04-30, 1396/02/10

Trial completion date

empty

Scientific title

Comparative survey of nebulized morphine and intravenous morphine for decreasing renal colic patients' pain

Public title

Comparative survey of nebulized morphine and intravenous morphine in renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patient above 18 years old severe pain caused by renal colic assigned by U/A severe pain caused by US

Exclusion criteria:

Morphine sensitivity SO₂<95 RR<12 SBP<110 rhinitis nose blocking asthma gainig analgesic 6 hours before admit

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Convenience sampling by filling up the questionnaire achieves to finish the process. Randomization is individual and Emergency department nurse, enters the samples to each therapy processes.

Blinding (investigator's opinion)

Double blinded

Blinding description

When a case enters, the nurse allocates the patient into case and control groups using a coin. He/She treats case or control. Then another nurse fills up the questionnaire . At the end the outcome assessor classified the questionnaire.

Placebo

Used

Assignment

Parallel

Other design features

"VAS" is used for pain measurement.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi Uni , Bahonar Sq

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2016-08-05, 1395/05/15

Ethics committee reference number

IR.SSU.MEDICINE.REC.1395.182

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 caused by renal colic

Timepoint

0-10-20-30 minutes after starting remedy

Method of measurement

using Visual Analogue Scale

Secondary outcomes

empty

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

intervention group:10 mg morphine nebulize and 5cc normal saline iv

Category

Treatment - Drugs

2**Description**

Control group: 5 mg morphine iv and 5cc normal saline nebulize

Category

Treatment - Drugs

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

Shahid Sadoghi & Rahnemoun Hospital

Full name of responsible person

Ali Saadatyar

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Ali Saadatyar

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Mehrnaz Nikouiie

Position

Professor

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All of information is sharable

When the data will become available and for how long

beginning access from 2018

To whom data/document is available

university researcher

Under which criteria data/document could be used

I havn't think about it yet.

From where data/document is obtainable

Myself.mobile number:+989133560517

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

Shahid Sadoughi university,uni research assistant-
medicine school research assistant,emergency medicine
group research assistant , DrNikouie ,Dr Saadat Yar

Comments