

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparing the analgesic effects and complications of morphine plus very low dose of naloxone with morphine alone on renal colic patients

Protocol summary

Summary

Objective: Since the higher quality of pain control with less complication is always an important issue in emergency departments, this study aims to compare the effects and complications of narcotic and narcotic in addition to naloxone. Design: A double-blind randomized clinical trial in which randomization will be performed using the random number table. Inclusion criteria: Renal colic and pain score of 7-10 based on VAS. The exclusion criteria are pregnancy, sensitivity to the drugs used in the study, morphine contraindications, history of drug dependence, receiving a calmativ drug during 6 hours before the visit, peritoneal symptoms in abdominal examination, history of cardiovascular diseases, psychosis and patient withdrawal to participate in the study, acute ischemic disease, age above 60, absence of renal colic in further studies. Sample size: 280 subjects. Intervention: A group of patients with renal colic will receive morphine (0.1 mg / kg) and placebo through a double-blind random method and the other group will receive the same dose of morphine with naloxone (0.001 mg/kg). An additional dose of 0.05 mg/kg morphine will be given to both groups after twenty minutes if needed (no pain control). Duration of intervention: From the beginning of admission to the emergency department. Primary outcomes: Pain, nausea, sedation, number of breaths, and blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031923696N5**

Registration date: **2017-08-17, 1396/05/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-17, 1396/05/26

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the analgesic effects and complications of morphine plus very low dose of naloxone with morphine alone on renal colic patients

Public title

Comparing the effect of morphine with combined morphine and naloxone on pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: renal colic; the severity of pain according to VAS should be 7 to 10. Exclusion criteria: pregnancy; allergies to medications used in the study; morphine contraindications; addicted to drugs; get analgesic in 6 hours prior to the study; the presence of symptoms of peritoneal in abdominal examination; history of cardiovascular disease; psychosis; unwillingness to participate in the study; acute ischemic disease; age over 60 years.

Age

From **84 years** old to **34 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, the randomization of random number table was used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for research, Mazandaran University of Medical Sciences, Moalem Square, Sari, Iran

City

Sari

Postal code

Approval date

2017-02-25, 1395/12/07

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITA.REC95.2627

Health conditions studied

1

Description of health condition studied

renal colic

ICD-10 code

n20,n21,n2

ICD-10 code description

Calculus of kidney, Calculus of lower urinary tract, Calculus of urinary tract in diseases classified elsewhere, Unspecified renal colic

Primary outcomes

1

Description

Pain

Timepoint

At the beginning of the intervention, 20, 40, 60, 120, 180 min after intervention

Method of measurement

VAS Scoring (visual analogue scale)

Secondary outcomes

1

Description

Blood pressure

Timepoint

0, 20, 40, 60, 120 and 180 min after intervention

Method of measurement

Mercury Sphygmomanometer

2

Description

Sedation

Timepoint

0, 20, 40, 60, 120 and 180 min after intervention

Method of measurement

Ramsay sedation scale

3

Description

Nausea

Timepoint

0, 20, 40, 60, 120 and 180 min after intervention

Method of measurement

VAS (visual analogue scale)

Intervention groups

1

Description

Intervention group: Morphine, manufactured by Dr Abidi Laboratory, 0.1 mg/kg intravenous injection, at min 0 and min 20, and Naloxone, manufactured by Dr Abidi Laboratory, 0.001 mg/kg intravenous injection, single dose, at min 0.

Category

Treatment - Drugs

2**Description**

Intervention group: Morphine, manufactured by Dr Abidi Laboratory, 0.1 mg/kg intravenous injection, at min 0 and min 20, and distilled water, manufactured by Dr Abidi Laboratory, 5 ml, intravenous injection, single dose, at min 0.

Category

Placebo

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

Emam Khomeini hospital of Sari

Full name of responsible person

Mehdi Muhammadianamiri

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Emergency Medicine Department, Imam Khomeini Hospital, Amir Mazandarani Street, Sari, Iran

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

Vice chancellor for research of Mazandaran 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

Vice chancellor for research of Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Mehdi Muhammadian Amiri

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Emergency medicine resident

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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