

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparative assessment of analgesic and complications of intravenous morphine and placebo with intravenous naloxon and morphine in renal colic patients

Protocol summary

Summary

In this double blind study, we will select two groups of 150 renal colic patients; with 18-69 years old age and Pain score, equal or more than 40 or 4 in VAS or NRS system, respectively; according to Balanced Block Randomization method and inclusion and exclusion criteria. Inclusion criteria include : age 18-69 years old Pain score equal or more than 40 or 4 in VAS or NRS system, respectively; and Exclusion criteria include: Pyelonephritis or fever equal or more than 38 degree centigrade, History of addiction or opioid allergy, History of cardiovascular disease (function class 3-4 or decompensated CHF or uncontrolled hypertension) , History of active hepatobiliary disorders Hemodinamically unstable patients (BP below 90mmHg or MAP decreased more than 30% baseline), Pregnancy and Breast feeding and History of CVA in last 2 years. Group A will receive 1 cc saline as placebo and group B will receive 1 CC of low dose naloxone (0.04 mg) intravenously. 5 minutes later, both groups will receive 2.5 mg morphine sulfate intravenously. Then we will follow the patients according to their pain score and complications every 15 minutes for about 90 min. If the pain score does not diminish below 4, we will administer other doses of morphine (max dose: 10 milligram). If despite the Morphine administration (max dose: 10 mg), pain score remains more than the mentioned threshold, the patient will exclude from the study but his pain management will continue. During this study, we will assess if naloxone could diminish the pain score and total dose of morphine administration in according to lower complications than morphine and placebo in renal colic patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106146804N1**

Registration date: **2011-12-17, 1390/09/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-17, 1390/09/26

Registrant information

Name

Mohammad Javad Behzadnia

Name of organization / entity

Baghyatallah medical sciences university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research , Baghyatallah Medical Sciences University.

Expected recruitment start date

2011-12-10, 1390/09/19

Expected recruitment end date

2012-04-07, 1391/01/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of analgesic and complications of intravenous morphine and placebo with intravenous naloxon and morphine in renal colic patients

Public title

Assessment of efficacy and complication of morphine and naloxan in renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include : age 18-69 years old; Pain score equal or more than 40 or 4 in VAS or NRS system, respectively; and Exclusion criteria include: Pyelonephritis or fever equal or more than 38 degree centigrade; History of addiction or opioid allergy; History of cardiovascular disease (function class 3-4 or decompensated CHF or uncontrolled hypertension) ; History of active hepatobiliary disorders ; Hemodinamically unstable patients (BP below 90mmHg or MAP decreased more than 30% baseline) ;Pregnancy and Breast feeding and History of CVA in last 2 years.

Age

From **18 years** old to **69 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baghyatallah medical sciences university ethics committee

Street address

3rd floor, Central department, Baghyatallah Medical Sciences University, Vice Chancellor for research, Nosrati alley, Sheikh Bahaie Molla St, Sadra St, Vanaq sq, Tehran, Iran

City

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Postal code

1435916471

Approval date

2011-12-01, 1390/09/10

Ethics committee reference number

6702-17 بند

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 severity

Timepoint

Every 15 min during 90 min

Method of measurement

Questionnaire, according to VAS or NRS pain score systems

Secondary outcomes

1

Description

Side effects

Timepoint

Every 15 min during 90 min

Method of measurement

Questionnaire, according to physical examination and patients observation

Intervention groups

1

Description

150 renal colic patients in group B (intervention group), with 18-69 years old age and Pain score, equal or more than 40 or 4 in VAS or NRS system, respectively, will receive 1 CC of low dose naloxone (0.04 mg) intravenously in similar syringes. 5 minutes later, this group will receive 2.5 mg morphine sulfate intravenously. Then we will follow the patients according to their pain score and complications every 15 minutes for about 90 min. If the pain score does not diminish below 4, we will administer other doses of morphine (max dose: 10 milligram). If despite the Morphine administration (max dose: 10 mg), pain score remains more than the mentioned threshold, the patient will exclude from the study but his pain management will

continue.

Category

Treatment - Drugs

2**Description**

150 renal colic patients in Group A (control group); with 18-69 years old age and Pain score, equal or more than 40 or 4 in VAS or NRS system, respectively, will receive 1 cc saline as placebo intravenously. 5 minutes later, this group will receive 2.5 mg morphine sulfate intravenously. Then we will follow the patients according to their pain score and complications every 15 minutes for about 90 min. If the pain score does not diminish below 4, we will administer other doses of morphine (max dose: 10 milligram). If despite the Morphine administration (max dose: 10 mg), pain score remains more than the mentioned threshold, the patient will exclude from the study but his pain management will continue.

Category

Treatment - Drugs

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

Baghyatallah hospital

Full name of responsible person

Dr Mohammad Javad Behzadnia

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

Vice Chancellor for research , Baghyatallah Medical Sciences University.

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 , Baghyatallah Medical Sciences University.

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**

Baghyatallah Medical Sciences University

Full name of responsible person

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Position

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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