

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of sublingual buprenorphine and acute kidney pain in patients with renal colic Hospital Emergency Department

Protocol summary

Summary

The study, a randomized double-blind controlled clinical trial, which will determine the effect of sublingual buprenorphine on pain of renal colic in patients with acute renal colic admitted to the hospital emergency department of Imam Khomeini's Sari accepts. For the study after obtaining necessary permits and after getting consent and explain to patients about the study, 196 patients with acute renal colic were randomly selected. Inclusion criteria: Clinical symptoms of renal colic with hematuria at least one of three in a urine analysis test, see stone radiography (Kidney Ureter Bladder = KUB) or ultrasound of the urinary Hungarian. Exclusion criteria: Heart disease, liver and kidney (except for kidney stones) Insensitivity to buprenorphine. Previous seizure history. Using random allocation to two groups (98 patients) and control (n = 98) are divided. For patients with sublingual buprenorphine tablets manufactured by Faran chemistry as sublingual 2 mg intravenously at a rate of 5 ml with distilled water as a placebo will be administered. To control the amount of morphine 1.0 mg per kg body weight will be administered a sublingual placebo pills. The pain and nausea and vomiting before, and at intervals of 20, 40 and 60 minutes after intervention were assessed and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082023696N1**

Registration date: **2015-10-21, 1394/07/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-21, 1394/07/29

Registrant information

Name

Seyed Mohammad Hosseininejad

Name of organization / entity

Mazandaran University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Mazandaran University Of Medical Science

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2015-10-30, 1394/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sublingual buprenorphine and acute kidney pain in patients with renal colic Hospital Emergency Department

Public title

The effect of sublingual buprenorphine and acute kidney pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Clinical symptoms of renal colic with

hematuria of at least one of the three tests on a urine analysis, x-ray view stone Or ultrasound of the Hungarian urine; Insensitivity to buprenorphine. Exclusion criteria: Previous seizure history; Heart disease, liver and kidney (except for kidney stones); Drug addiction; See a history of frequent (more than 3 times a year) because of acute renal colic emergency department ; Pregnancy; Patients with fever (temperatures over 38 ° C); Hypersensitivity to opioid; The patient hemodynamically unstable (systolic blood pressure less than 90 mm Hg); Get pain medication at 6 hours prior to admission to the emergency department.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 196

Randomization (investigator's opinion)

N/A

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**

Mazandaran University Of Medical Science

Street address

Mazandaran, Sari

City

Sari

Postal code**Approval date**

2015-08-31, 1394/06/09

Ethics committee reference number

1159.Code: IR.MAZUMS.REC.94

Health conditions studied**1****Description of health condition studied**

acute renal colic pain

ICD-10 code

N23

ICD-10 code description

acute renal colic pain

Primary outcomes**1****Description**

Renal colic pain

Timepoint

Half an hour and an hour after intervention

Method of measurement

Questionnaire and vAS

Secondary outcomes

empty

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

Individually prescribed two painkillers

Category

Treatment - Drugs

2**Description**

For patients with sublingual buprenorphine tablets manufactured by Faran chemistry as sublingual 2 mg intravenously at a rate of 5 ml with distilled water as a placebo will be administered

Category

Treatment - Drugs

3**Description**

To control the amount of morphine 1.0 mg per kg body weight will be administered a sublingual placebo pills

Category

Treatment - Drugs

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

Imam Khomeini Hospital

Full name of responsible person

Dr Seyed Mohammad Hoseininejad

Street address**City**

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University Of Medical Science

Full name of responsible person

Ahmad Ali Enayati

Street address

Mazandaran, Sari, Mazandaran University Of Medical Science

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University Of Medical Science

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 Univercity Of Medical Science

Full name of responsible person

Dr Abolhassan Samakosh

Position

Resident Emergency Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University Of Science

Full name of responsible person

Dr Seyed Mohammad Hoseininejad

Position

Emergency medicine specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Orthopedics Research Center, Mazandaran University Of Science

Full name of responsible person

Samira Aghajani

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Web page address

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