Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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

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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
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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