Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of Sublingual Buprenorphine and IV Ketorolac Analgesic Effect in Patients with Renal Colic Presented to Emergency Department

Protocol summary

Summary

This study conductes to comparison of Sublingual Buprenorphine and IV Ketorolac Analgesic Effect in Patients with Renal Colic Present to Emergency Department.This study is a double-dummy, comparisonal randomized clinical trial. Inclusion Criteria: patient with both gender؛ Age through 18-55 years old؛ Severity pain of renal colic in Visual Pain Analog Scale must be 3-10. Clnical Criteria: Nephrolithiasis history؛ Severity pain in loin region , Dysuria, Laboratory Criteria: Urinary Analysis (+) Imaging Criteria: Confirm of stone with Computed Tomography without contrast or sonography. Exclusion Criteria: Decreased level of consciousness؛ Cardiac problems؛ Chronic Renel diseases؛ Hepatic and Respiratory diseases؛ Allergy to Opioieds؛ Resiving of analgesic drug in passed 6 hours؛ History of seizure؛ Pregnancy؛ Addiction؛ Abdominal tenderness؛ History or active Gastrointestinal Bleeding. The samples selecte from pateints with renal colic that present to emergency department of Ahvaz Golestan hospital. The time consume of this study is 3 months and 62 peoples enrolle for working. Drug intervention carry out in two groups as each group, resives drug and placebo. Group1: sublingual buprenorphine (tab 0.4 mg) with IV sterile water (placebo) and Group2: IV ketorolac (30 mg) with sublingual placebo. At 0, 20, 40 and 60 minutes after administration,from patient, aske to rate their pain from 0- 10 scales.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041421773N1**
Registration date: **2015-05-09, 1394/02/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-05-09, 1394/02/19

Registrant information

Name
Marzieh Dezham
Name of organization / entity
Assistant Professor of Emergency Medicine
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Recruitment status

Recruitment complete

Funding source

Jondishapour University of Medical Sciences, Mdicine Faculty, Department of Assistance Research

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Sublingual Buprenorphine and IV Ketorolac Analgesic Effect in Patients with Renal Colic Presented to Emergency Department

Public title

The comparison of Buprenorphine and Ketorolac Analgesic Effect in Patients with Renal Colic

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: patient with both gender؛ Age through 18-55 years old؛ Severity pain of renal colic in Visual Pain Analog Scale must be 3-10. Clnical Criteria: Nephrolithiasis history؛ Severity pain in loin region , Dysuria, Laboratory criteria: Urinary Analysis (+) Imaging Criteria: Confirm of stone with Computed Tomography without contrast or sonography. Exclusion Criteria: Decreased level of consciousness؛ Cardiac problems؛ Chronic Renel diseases؛ Hepatic and Respiratory diseases؛ Allergy to Opioieds؛ Resiving of analgesic drug in passed 6 hours؛ History of seizure؛ Pregnancy؛ Addiction؛ Abdominal tenderness؛ History or active Gastrointestinal Bleeding.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

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

Jundishapour University of Medical Sciences - Ethics Committee

Street address

Ethics Committee- Jundishapour University- Ahvaz- Iran

City

Ahvaz

Postal code

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

ajums.REC.1393.433

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

n20.9

ICD-10 code description

urinary calculus, unspecified

Primary outcomes

1

Description

Pain

Timepoint

0, 20, 40 and 60 minets after drug intervention

Method of measurement

Visual Pain Analog Scale

Secondary outcomes

1

Description

Adverse Effects

Timepoint

0, 20, 40 and 60 minets after drug intervention

Method of measurement

Clinical examination, Observation and asking from patient

Intervention groups

1

Description

Drug intervention carry out in two groups as each group, resives drug and placebo. Group1: sublingual buprenorphine (tab 0.4 mg) with IV sterile water (placebo)

Category

Treatment - Drugs

2

Description

Drug intervention carry out in two groups as each group, resives drug and placebo. Group2: IV ketorolac (30 mg) with sublingual placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Ahvaz hospital, Emergency department
Full name of responsible person
Dr. Javad Mozafari
Street address
Golestan Ahvaz hospital, Emergency department
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Department of Assistance Research- Jundishapour University of Medical Sciences
Full name of responsible person
Dr. Nadre Saki
Street address
Department of Assistance Research of medical faculty- Jundishapour university of Medical Sciences
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Department of Assistance Research- Jundishapour 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
Emergency Department- Medicine faculty- Jundishapour University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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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