

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison between the clinical efficacy of Intravenous Fentanyl and Ketorolac in relieving renal colic pain

Protocol summary

Study aim

Comparison between the clinical efficacy of Intravenous fentanyl and ketorolac in reliving renal colic pain and choosing a more appropriate drug with less side effects.

Design

Patients will be examined after obtaining a consent, history and demographic information. Eligible patients entering the study are randomly divided into two groups by permuted balanced block randomization. A group receive intravenous fentanyl and another group receive of intravenous ketorolac. Dosage are determined based on similar studies and responses to their treatment. Patients receive 5 mg of IM morphine if the VAS rate exceeds 50% after 60 minutes. The severity of the pain is measured by the VAS questionnaire. The body temperature, HR, BP, and VAS are recorded before treatment and then at intervals of 20 minutes to 60 minutes. Patients are also screened for side effects of drugs. Calculations were performed using G * power software.

Settings and conduct

The study was designed in patients with renal colic as a single blind in Kowsar Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with unilateral abdominal or flank pain suspect to renal colic that confirm by paraclinics or the stone passage by the patient. Exclusion criteria: En Visual Analog Scale ≤ 3 ; history of peptic ulcer disease, asthma and bleeding disorder; using of oral anticoagulant, sedative, antipsychotic, MAO-I, painkillers within 6 hours before; impaired renal or hepatic function. hypersensitivity to Aspirin or NSAID or Fentanyl; pregnant or breast-feeding women; younger than 18 and greater than 55 years old.

Intervention groups

Treatment of patients with acute colic pain with intravenous fentanyl and ketorolac

Main outcome variables

Determining and comparing the clinical efficacy of

intravenous ketorolac and fentanyl in relieving pain in renal colic patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150902023855N3**

Registration date: **2020-07-14, 1399/04/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-14, 1399/04/24**

Update count: **0**

Registration date

2020-07-14, 1399/04/24

Registrant information

Name

Davood Arab

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-03, 1399/03/14

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison between the clinical efficacy of Intravenous Fentanyl and Ketorolac in relieving renal colic pain

Public title
Comparison between the clinical efficacy of Intravenous Fentanyl and Ketorolac in relieving renal colic pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with a history of unilateral abdominal or flank pain that the treating emergency physicians suspect to be renal colic Ultrasonography or CT Scan or intravenous pyelography (IVP) findings consistent with the diagnosis of renal stone Stone excretion
Exclusion criteria:
 Visual Analog Scale (VAS) ≤ 3 History of peptic ulcer disease History of asthma History of bleeding disorder Using of oral anticoagulant Impaired renal or hepatic function Hypersensitivity to Aspirin or NSAID or Fentanyl Pregnant and breast-feeding women Received Sedative, Antipsychotic, MAO-I, painkillers within 6 hours before Younger than 18 and greater than 55 years old

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be examined after obtaining a diagnosis and demographic information. Eligible patients entering the study are randomly divided into two groups by permuted balanced block randomization. And the randomization list will be prepared using block stratified randomization software for windows version 6.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study is designed as single blind and only patients were blind in this study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Kosar Hospital, Bassije Blvd, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.SEMUMS.REC.1399.067

Health conditions studied

1

Description of health condition studied

Acute Renal Colic

ICD-10 code

Calculus o

ICD-10 code description

N20.2

Primary outcomes

1

Description

Pain level

Timepoint

Before treatment initiation and sequentially at 20, 40, 60 minutes

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

heart rate

Timepoint

Before treatment initiation and sequentially at 20, 40, 60 minutes

Method of measurement

Radial puls

2

Description

Blood pressure

Timepoint

Before treatment initiation and sequentially at 20, 40, 60 minutes
Method of measurement
Sphygmomanometer

3

Description
Body temperature
Timepoint
Before treatment initiation and sequentially at 20, 40, 60 minutes
Method of measurement
Thermometer(axillary)

4

Description
Respiratory rate
Timepoint
Before treatment initiation and sequentially at 20, 40, 60 minutes
Method of measurement
Physical exam

5

Description
Fentanyl side effects
Timepoint
In all the time in care
Method of measurement
Questionnaire and physical examination

6

Description
Ketorolac side effect
Timepoint
In all the time in care
Method of measurement
Questionnaire and physical examination

Intervention groups

1

Description
Intervention group 1: patients will receive 0.1mg intravenous Fentanyl (Darou Pakhsh Pharmaceutical company) infused in 100 ml normal saline within 10 minutes.
Category
Treatment - Drugs

2

Description
Intervention group 2: patients will receive 30mg intravenous Ketorolac(Alborz Darou Pharmaceutical company) within 15 seconds.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Medical Center
Full name of responsible person
Dr Davood Arab
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Kosar Hospital, Bassij Blvd, Semnan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Parviz Kokhaie
Street address
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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
Semnan University of Medical Sciences
Proportion provided by this source
100
Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Davood Arab
Position
fellowship of Endourology
Latest degree
Specialist
Other areas of specialty/work
Urology
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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