

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Atomized intranasal vs intravenous fentanyl for acute Renal colic management in ED: A randomized double-blinded clinical trial

Protocol summary

Study aim

Comparison of intranasal and intravenous fentanyl to control acute renal colic pain in emergency department

Design

In this study, 120 patients who referred to the Emergency Department with symptoms of acute renal pains are included in the study. Participants are divided into two groups in terms of drug use. To balance the two groups, the minimization method is used.

Settings and conduct

This is the multicenter study will be done in Kerman, southeastern Iran. By minimization, patients are divided into two groups. A group will receive intravenous fentanyl and intramuscular ketorolac and the second group intranasal fentanyl and intramuscular ketorolac. The nurse will prescribe medication and determine the type of medication prescribed by the physician. Data collection will be done by another physician.

Participants/Inclusion and exclusion criteria

All patients with acute renal colic symptoms aged 16 to 65 years are included in the study, and patients who have a possible other diagnosis or have a drug allergy or organ failure and kidney transplantation are excluded.

Intervention groups

One group received fentanyl intravenous (1micro/kg) and intramuscular ketorolac (30 mg IM) and the second group received intranasal fentanyl (3 micro/kg) and intramuscular ketorolac (30 mg IM).

Main outcome variables

Procedural time, pain stop time, patient and physician satisfaction, side effects of the drug, the need for more doses of the drug, recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150509022181N4**

Registration date: **2019-06-19, 1398/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-19, 1398/03/29**

Update count: **0**

Registration date

2019-06-19, 1398/03/29

Registrant information

Name

Mehdi Torabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 199 2016

Email address

mtorabi1390@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Atomized intranasal vs intravenous fentanyl for acute Renal colic management in ED: A randomized double-blinded clinical trial

Public title

Atomized intranasal vs intravenous fentanyl for acute
Renal colic management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

16-65 years old clinical symptoms of acute renal colic
visual analog scale (VAS) greater than or equal to 7

Exclusion criteria:

allergy to opiates and NSAIDs known or suspected
abdominal aortic dissection or aneurism peritonitis
hemodynamic instability pregnancy, breastfeeding
anticoagulant therapy organs failure renal
transplantation

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomized by minimization to a 1:1 ratio to
receive either intranasal or intravenous fentanyl in a
double-blinded fashion (physician and analyzer). Patients
with pain intensity are divided according to VAS, which is
not significantly different between the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The physician for data collection and data analyzer are
blinded about 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 Kerman University of Medical
Science

Street address

Gharani Ave, Bahonar academic hospital

City

Kerman

Province

Kerman

Postal code

7619736555

Approval date

2018-12-27, 1397/10/06

Ethics committee reference number

IR.KMU.AH.REC.1397.116

Health conditions studied

1

Description of health condition studied

Acute renal colic

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

Pain control time

Timepoint

At the beginning of the study, 10, 20, 30, 40, 60 minutes
after the administration of the drug

Method of measurement

VAS (Visual Analog Scale)

Secondary outcomes

1

Description

The physician and patient satisfaction

Timepoint

The end of study

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: In the intervention group, fentanyl
was administered intranasally with intravenous placebo.
Fentanyl, a sublimaz brand, was prescribed at a dose of
1 microgram per kilogram.

Category

Treatment - Drugs

2

Description

Control group: The control group received placebo
intranasally with intravenous fentanyl. Fentanyl, a

sublimaz brand, was prescribed at a dose of 1 microgram per kilogram.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar academic hospital

Full name of responsible person

Mehdi Torabi

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Gharani ave.

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Torabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Kerman University of Medical Sciences

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual and outcome data will be provided

When the data will become available and for how long

One year after the publication of the article

To whom data/document is available

Academic Institutions

Under which criteria data/document could be used

Clinical research

From where data/document is obtainable

email

What processes are involved for a request to access data/document

Two weeks after receiving the request email, the results will be e-mailed.

Comments