

# 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

**Street address**

Gharani ave.

**City**

Kerman

**Province**

Kerman

**Postal code**

7613747181

**Phone**

+98 34 3223 5011

**Email**

mtorabi1390@yahoo.com

**2**

**Recruitment center**

**Name of recruitment center**

Afzalipour academic hospital

**Full name of responsible person**

Mehdi Torabi

**Street address**

Emam Blvd.

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913911

**Phone**

+98 34 3132 8000

**Email**

mtorabi1390@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Abbas Pardakhti

**Street address**

Ebnesina Ave.

**City**

Kerman

**Province**

Kerman

**Postal code**

7619813159

**Phone**

+98 34 3226 3855

**Email**

abpardakhty@kmu.ac.ir

**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

**Street address**

Gharani Ave.

**City**

Kerman

**Province**

Kerman

**Postal code**

7613747181

**Phone**

+98 34 3223 5011

**Email**

mtorabi1390@yahoo.com

**Person responsible for scientific 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  
**Street address**  
Gharani Ave.  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7613747181  
**Phone**  
+98 32235011  
**Email**  
mtorabi1390@yahoo.com

## Person responsible for updating data

**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  
**Street address**  
Gharani Ave.  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7613747181

**Phone**  
+98 34 3223 5011  
**Email**  
mtorabi1390@yahoo.com

## 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