

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 2026

### study of the analgesic effect of fentanyl, fentanyl with ibuprofen, fentanyl with apotel and fentanyl with ketorolac on the reduction of pain and duration of hospitalization in patients with renal colic

#### Protocol summary

##### Study aim

Comparison of analgesic effect of fentanyl alone with simultaneous administration of fentanyl with ibuprofen, apotel and ketorolac on pain reduction and duration of hospitalization of renal colic patients referred to emergency department of Ayatollah Kashani Hospital in Shahrekord

##### Design

The clinical trial with control groups, with parallel, double-blind, randomized, phase 2 groups on 200 patients

##### Settings and conduct

All patients referred to Kashani Hospital in Shahrekord with renal colic will be selected for a sample of 200 people and according to the randomly blocked allocation method, patients will be randomly assigned to 4 groups (F: fentanyl alone, FK: fentanyl and ketorolac, FA: Fentanyl and Apotel, FI: Fentanyl and ibuprofen) will be divided into a way that the researcher and patient are unaware of the type of intervention.

##### Participants/Inclusion and exclusion criteria

All patients over the age of 18 years and stable hemodynamics referred to Kashani Hospital in Shahrekord with renal colic in 2022-2023 will be the study population.

##### Intervention groups

Group F: Patients who receive fentanyl at a dose of 50 µg (Darou Pakhsh Company) in the form of intravenous infusion. Group FK: Patients who receive fentanyl at a dose of 50 µg (Darou Pakhsh Company) in the form of intravenous infusion and ketorolac (Alborz Company) with a dose of 30 mg in rapid infusion within 15 seconds. FA Group: Patients who receive fentanyl at a dose of 50 µg (Darou Pakhsh Company) and apotel (Elixir Company) with a dose of 1 gram per 100 cc normal saline within 20 minutes in the form of intravenous infusion. FI Group: Patients who receive fentanyl at a dose of 50 µg (Darou

Pakhsh Company) and ibuprofen (Caspian Company) in 300 mg intravenous infusion.

##### Main outcome variables

Blood pressure, heart rate, blood oxygen percentage, respiratory rate; ketorolac, fentanyl, apotel and ibuprofen side effects

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220421054605N1**

Registration date: **2022-05-31, 1401/03/10**

Registration timing: **prospective**

Last update: **2022-05-31, 1401/03/10**

Update count: **0**

##### Registration date

2022-05-31, 1401/03/10

##### Registrant information

##### Name

Fatemeh Zahedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 007 9760

##### Email address

zahedifatemeh744@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-10, 1401/03/20

##### Expected recruitment end date

2022-12-21, 1401/09/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
study of the analgesic effect of fentanyl, fentanyl with ibuprofen, fentanyl with apotel and fentanyl with ketorolac on the reduction of pain and duration of hospitalization in patients with renal colic

**Public title**  
study of the analgesic effect of fentanyl, fentanyl with ibuprofen, fentanyl with apotel and fentanyl with ketorolac in patients with renal colic

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients over the age of 18 have renal colic have stable hemodynamics(pulse rate(PR)=60-100,systolic blood pressure(SBP)>100,respiratory rate(RR)=8-22,functional oxygen saturation(SPO2)>90%) Have informed consent to participate in this study Don't have any of the following: Pregnancy/Asthma / chronic obstructive pulmonary disease(COPD)/ Intestinal obstruction/ Hypertension and heart failure/ Previous pulmonary surgery of the kidney and urinary tract/ Peptic ulcer/ Gastrointestinal bleeding/ Previous allergies to fentanyl or other analgesics / Loss of consciousness/ Trauma Head and chest/pneumocephalus/pneumothorax/Drug addiction/tenderness and abdominal rebound/Guarding abdomen/menstruation retarded/Use of analgesics in the past 24 hours No liver failure and bilateral renal failure  
**Exclusion criteria:**

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**  
Target sample size: **200**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, 200 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". These numbers are randomly divided into four groups A (first intervention) , B (second intervention) , C (Third intervention) and D ( fourth intervention). Each number is written on paper and placed in an envelope. Then each

patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the four groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, fentanyl , ibuprofen , ketorolac and apotel, will be prepared by an emergency medicine specialist and placed in coded packages and delivered daily to the researcher, who will prescribe them without knowing the type of each drug. They do. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Shahre-Kord University of Medical Sciences  
**Street address**  
Shahrekord University Of Medical Sciences, Kashani Blvd  
**City**  
Shahrekord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8815713471

**Approval date**  
2022-01-09, 1400/10/19

**Ethics committee reference number**  
IR.SKUMS.REC.1400.071

**Health conditions studied**

**1**

**Description of health condition studied**  
Renal colic

**ICD-10 code**  
N23

**ICD-10 code description**  
Unspecified renal colic

**Primary outcomes**

**1**

**Description**

Pain score

#### **Timepoint**

At the beginning of the study and at 5, 10, 15, 20, 25 and 30 minutes after the intervention

#### **Method of measurement**

Visual Analogue Scale (VAS)

## **Secondary outcomes**

### **1**

#### **Description**

Mean Arterial Pressure

#### **Timepoint**

At the beginning of the study and at 5, 10, 15, 20, 25 and 30 minutes after the intervention

#### **Method of measurement**

Monitoring device

### **2**

#### **Description**

Hear rate

#### **Timepoint**

At the beginning of the study and at 5, 10, 15, 20, 25 and 30 minutes after the intervention

#### **Method of measurement**

Monitoring device

### **3**

#### **Description**

Percentage of blood oxygen

#### **Timepoint**

At the beginning of the study and at 5, 10, 15, 20, 25 and 30 minutes after the intervention

#### **Method of measurement**

Monitoring device

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: In this group, fentanyl (Darou Pakhsh Company) with a dose of 50 µg is administered as intravenous infusion.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group 2: For patients in this group, fentanyl (Darou Pakhsh Company) at a dose of 50 µg and ketorolac (Alborz Company) at a dose of 30 mg is administered intravenously.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Intervention group 3: For patients in this group, fentanyl (Darou Pakhsh Company) with a dose of 50 µg and Apotel (Elixir Company) with a dose of 1 g/100 cc normal saline, will be administered in 20 minutes as intravenous infusion.

#### **Category**

Treatment - Drugs

### **4**

#### **Description**

Intervention group 4: For patients in this group, fentanyl (Darou Pakhsh Company) with a dose of 50 mcg and ibuprofen (Caspian Company) is administered 300 mg in intravenous infusion.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Ayatollah Kashani Hospital

##### **Full name of responsible person**

Abdul Rahim Sane'i Dehkordy

##### **Street address**

Shahrekord University of Medical Sciences, Kashani street,

##### **City**

Sharekord

##### **Province**

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##### **Postal code**

8815713471

##### **Phone**

+98 38 3333 0061

##### **Email**

sanei.a@skums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shahre-kord University of Medical Sciences

##### **Full name of responsible person**

Esfandiar Heidari

##### **Street address**

Vice Chancellory for research, Shahrekord University Of Medical Sciences, Kashani Blvd

##### **City**

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##### **Province**

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+98 38 3334 2414

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zahedifatemeh744@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Shahre-kord 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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Abdul Rahim Sane'i Dehkordy

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Shahre-kord University of Medical Sciences, Kashani street,

**City**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Abdul Rahim Sane'i Dehkordy

**Position**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

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**Position**

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**Latest degree**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to

make this available  
**Data Dictionary**

Undecided - It is not yet known if there will be a plan to  
make this available