Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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Assistant Professor
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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