

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of nebulized Fentanyl versus intravenous Ketorolac in patients with renal colic: a double-blind randomized clinical trial

Protocol summary

Study aim

To compare the effect of nebulized Fentanyl versus intravenous Ketorolac in patients with renal colic

Design

This is a double-blind randomized clinical trial, phase II, in which 186 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with renal colic who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention 1 and 2 groups. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 12 to 80 years Renal colic
Exclusion criteria: Unstable hemodynamic Body temperature above 38 degrees centigrade Acute abdomen Heart failure and ischemic heart disease Renal failure Liver failure History of transplantation Pregnancy

Intervention groups

Intervention group 1: Nebulized Fentanyl 50 mcg as a single dose Intervention group 2: Intravenous Ketorolac 0.9 mg/kg as a single dose

Main outcome variables

Assessing renal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N273**

Registration date: **2019-05-04, 1398/02/14**

Registration timing: **retrospective**

Last update: **2019-05-04, 1398/02/14**

Update count: **0**

Registration date

2019-05-04, 1398/02/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2019-04-17, 1398/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of nebulized Fentanyl versus intravenous Ketorolac in patients with renal colic: a double-blind randomized clinical trial

Public title

Comparison of the effect of nebulized Fentanyl versus

intravenous Ketorolac in patients with renal colic

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 12 to 80 years Renal colic
Exclusion criteria:
Unstable hemodynamic Body temperature above 38 degree centigrade Acute abdomen Heart failure and ischemic heart disease Renal failure Liver failure A history of transplantation Pregnancy

Age
From **12 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **186**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to the intervention 1 group or intervention 2 group using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention 1 and on the other two sheets the name of the intervention 2. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2018-03-10, 1396/12/19
Ethics committee reference number
IR.UMSHA.REC.1396.889

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
Assessing the renal pain
Timepoint
Every 15 minutes for 2 hours
Method of measurement
Using Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Timepoint
Method of measurement

Intervention groups

1

Description
Intervention group 1: Nebulized Fentanyl 50 mcg as a single dose
Category
Treatment - Drugs

2

Description

Intervention group 2: Intravenous Ketorolac 0.9 mg/kg as a single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan City

Full name of responsible person

Dr. Alireza Kalantari

Street address

Besat Hospital, Shahed Square

City

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Postal code

6517838695

Phone

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Email

alirezakalantari1362@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza Kalantari

Position

Resident of Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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