Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of rectal Diclofenac sodium and intramuscular Pethidine injection on severity of acute renal colic pain

Protocol summary

Study aim

Comparison of the effect of sodium Diclofenac suppository and muscle Pethidine on the severity of acute colic renal

Design

In this double-blind clinical trial,72 people with colic renal,received one of the studied treatments with the opinion of a physician and were divided into two parallel groups.

Settings and conduct

the emergency department of Razi Hospital in Birjand؛from December 28 to February 30 Data were collected after the necessary investigations and obtaining consent to enter the research and fill out the checklist. Then,1: 1 was divided into two groups of 36 people,and demographic information was matched between the two groups.The first group was given a 100mg Diclofenac suppository and the second group was given a 50mg Pethidine ampoule,and information was collected using the VAS (Visual Analog Scale)system.

Participants/Inclusion and exclusion criteria

Inclusion criteria:People who go with acute renal colic. Exclusion criteria:peptic ulcer؛hemorrhoids and anal fissure؛ pregnancy؛IBD؛coagulopathy؛heart disease؛COPD؛liver disease؛asthma؛lactating women؛those who received analgesics 6 hours before entering the emergency room and allergies to NSAIDs.

Intervention groups

In this study,72 blind people with acute renal colic,who had similar pain due to the mental nature of the previous pain,Then,1:1 was divided into two groups of 36 people,and demographic information was matched between the two groups.The first group was given a 100mg diclofenac suppository and the second group was given a 50mg petadine ampoule.

Main outcome variables

Age,sex,pregnancy,weight,drug use;history of hemorrhoids and anal fissures;history of coagulopathy;inflammatory bowel disease;history of peptic ulcer;heart disease;liver disease;COPD;renal failure;NSAID susceptibility;warfarin use;diabetes;asthma;lactation;analgesia 6 hours before onset;pain pattern at onset;10,20 and 30 minutes after taking the drug.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047123N1**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Masoud Mozaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3276 3099

Email address

s.salehes1174@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

2020-02-19, 1398/11/30

Actual recruitment end date

2020-04-18, 1399/01/30

Trial completion date

2020-04-18, 1399/01/30

Scientific title

Comparison of the effects of rectal Diclofenac sodium and intramuscular Pethidine injection on severity of acute renal colic pain

Public title

Comparison of the effects of rectal diclofenac sodium and intramuscular pethidine injection on severity of acute renal colic pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

people who had similar pain with acute renal colic due to the mental nature of the previous pain

Exclusion criteria:

Peptic Ulcer Hemorrhoids and anal fissures Pregnancy COPD IBD Coagulopathy Heart disease Liver disease Asthma Breastfeeding Those who received painkillers 6 hours before entering the emergency room. Allergies to NSAIDs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the study received consent, but did not know which of the two drugs they were taking. Also, when evaluating the data, the analyst does not know the type of drug received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences,Ghaffari Blvd

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2020-02-02, 1398/11/13

Ethics committee reference number

IR.BUMS.REC.1398.329

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 intensity in Visual Analogue Scale system

Timepoint

Measure the severity of the pain at the beginning of the visit and 10, 20 and 30 minutes after receiving the drug

Method of measurement

Visual Analogue Scale system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group: 36 patients with colic Renal who receive a diclofenac suppository at a dose of 100 mg.

Category

Treatment - Drugs

2

Description

Intervention group: 36 patients with renal colic receiving a dose of 50mg of pethidine ampoules.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Seyed Masoud Mozaffari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Tooba Kazemi

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Masoud Mozaffari

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
In this study, after identifying people, all the information obtained from the variables can be shared.

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
Information is available to everyone

Under which criteria data/document could be used
Research projects

From where data/document is obtainable
Birjand University of Medical Sciences Postal code 9717853577 and address www.bums.ac.ir

What processes are involved for a request to access data/document
Send a request to the Research Committee of Birjand University of Medical Sciences

Comments