

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the efficacy and safety of pethidine, Diclofenac suppository and combination of them on duration of hospitalization of renal colic patients in Imam Reza Hospital Kermanshah 1389

Protocol summary

Summary

This study was a single blind randomized clinical trial performed to compare Pethidine, Diclofenac Suppository and a combination of these two drugs on Renal Colic pain in Emergency Department of Imam Reza Hospital. A total of 90 patients with acute renal colic, aged 18 to 60 years old, were randomly assigned to receive pethidine injection 50 mg, diclofenac suppository, 50 mg or combination the two drugs on arrival and 30 minutes later. The intensity of pain was measured at the baseline and 10 minutes after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012145389N1**

Registration date: **2011-03-24, 1390/01/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-03-24, 1390/01/04

Registrant information

Name

Soodeh Shahsavari

Name of organization / entity

university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6299

Email address

crdu@irhk.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2010-12-26, 1389/10/05

Expected recruitment end date

2011-02-24, 1389/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and safety of pethidine, Diclofenac suppository and combination of them on duration of hospitalization of renal colic patients in Imam Reza Hospital Kermanshah 1389

Public title

Efficacy of pethidine, Diclofenac suppository and combination of them on duration of hospitalization of renal colic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: clinical diagnosis of acute renal colic (colic Flank pain may be associated with urinary symptoms including urinary frequency, dysuria, or hamaturia. Other causes of flank pain should be ruled out by P/E or ultrasound), age 18 to 60 years, pain intensity more than 5 according to VAS Exclusion criteria: Pregnancy, breast feeding, analgesic consumption in six hours prior to the intervention, presence of renal failure, warfarin consumption, contraindication of NSAIDs or opioids consumption, presence of bleeding tendency, drug addiction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti Boulevard,
Kermanshah

City

Kermanshah

Postal code**Approval date**

2010-10-10, 1389/07/18

Ethics committee reference number

6638

Health conditions studied**1****Description of health condition studied**

Renal colic

ICD-10 code

N22

ICD-10 code description

Calculus of urinary tract in diseases classified elsewhere

Primary outcomes**1****Description**

pain

Timepoint

before and 30 minutes after the intervention

Method of measurement

vas scale

2**Description**

hospital stay

Timepoint

At discharge from hospital

Method of measurement

Registration records

Secondary outcomes**1****Description**

Hypertension

Timepoint

15,30, and 40 minutes after the intervention

Method of measurement

sphygmomanometer

2**Description**

Nausea

Timepoint

15,30, and 40 minutes after the intervention

Method of measurement

Asking from the patient

Intervention groups**1****Description**

Pethidine, 50 mg IV injection, on arrival and 30 minutes later

Category

Treatment - Drugs

2**Description**

Diclofenac, 50 mg Suppository, on arrival and 30 minutes later

Category

Treatment - Drugs

3**Description**

Pethidine, 50 mg IV injection as well as Diclofenac, 50 mg Suppository, on arrival and 30 minutes later

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Imam Reza Hospital

Full name of responsible person

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr Farid Najafi

Street address

Building No.2, Shahid Beheshti Bouelvard, Kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr Ali Taherinia

Position

Emergency Medicine Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Other areas of specialty/work

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Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Soodeh Shahsavari

Position

MS in Biostatistics/Clinical Research Department Unit

Other areas of specialty/work

Street address

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City

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Postal code

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Fax

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty