Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Bouelvard, 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
befoer 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
Street address
Imam Reza Hospital
City
Kermanshah
Postal code
Phone
+98 83 1427 6299
Fax
Email
dr_alitaheri@yahoo.com
Web page address

Person responsible for scientific 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
Street address
Imam Reza Hospital
City
Kermanshah
Postal code
Phone
+98 83 1427 6299
Fax
Email
dr_alitaheri@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences and Heath Services
Full name of responsible person
Soodeh Shahsavari
Position
MS in Biostatistics/Clinical Research Department Unit
Other areas of specialty/work
Street address
Imam Reza Hospital
City
Kermanshah
Postal code
Phone
Fax
Email
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