Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Therapeutic effects of rectal Diclofenac sodium and intramuscular pethedine injection in the treatment of acute renal colic: A randomized clinical trial

Protocol summary

Summary

Renal colic is a common urological emergency at the emergency department, often caused by the movement of ureteral stones and characterized by severe pain. Patients describe this pain as the most severe and excruciating situation ever experienced this study is conducted to compare the efficacy of analgesic therapy of rectal diclofenac sodium (RD) and intramuscular pethidine (IMP), commonly preferred in emergency departments in our country in patients with renal colic. This study is conducted as a randomized clinical trial. Visual Analog Scale (VAS) would be used to measure primary outcome (pain). All patients with impression of renal stone aging between 17 to 55 will be included in the study. Cases will be divided into two groups randomly (simple randomization). 100 mg suppository Diclofenac will be administered for one group and 50 mg intra muscular Pethedin for another group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408129936N9**
Registration date: **2014-09-22, 1393/06/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-22, 1393/06/31

Registrant information

Name

Leila Ghahramani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1623 5586

Email address

lghahraman@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Shiraz, Iran and Jahrom University of Medical Sciences, Jahrom, Iran

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of rectal Diclofenac sodium and intramuscular pethedine injection in the treatment of acute renal colic: A randomized clinical trial

Public title

Therapeutic effects of rectal Diclofenac sodium and intramuscular pethedine injection in the treatment of acute renal colic: A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria; all patients with renal colic pain (with impression of renal stone); age between 17 to 55 years old. Exclusion criteria: allergy to NSAIDs; hemorrhoid; anal fissure; acid peptic disease; coagulopathy;

pregnancy; heart disease; COPD; liver failure; renal failure.

Age

From **17 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **600**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jahrom University of Medical Sciences, Jahrom, Iran

Street address

Jahrom University of Medical Sciences, Jahrom,Fars, Iran

City

Jahrom

Postal code

-

Approval date

2008-02-20, 1386/12/01

Ethics committee reference number

1386/123

Health conditions studied

1

Description of health condition studied

Renal colic (duo to renal stone)

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

The pain score in each group

Timepoint

10, 20, 30 and 60 minutes after using the drug (intervention)

Method of measurement

Numeric pain intensity scale (VAS Scoring system)

Secondary outcomes

empty

Intervention groups

1

Description

Suppository Diclofenac 100mg stat dose

Category

Treatment - Drugs

2

Description

Pethedin IM 50mg stat dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi hospital, Shiraz University of Medical Sciences

Full name of responsible person

Dr Leila Ghahramani- Assistant professor of General Surgery

Street address

Colorectal Research Center, Shahid Faghihi hospital, Shiraz University of Medical Sciences

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Seyed Basir Hashemi, MD

Street address

Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences, Shiraz, Iran
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
Colorectal Research Center, Shiraz university of medical sciences
Full name of responsible person
Leila Ghahramani, MD
Position
Colorectal flowship-assistant professor
Other areas of specialty/work
Street address
Colorectal Research Center, Shiraz university of Medical Siences, Shiraz
City
Shiraz
Postal code
Iran
Phone
+98 71 1230 6972
Fax
Email
leila_ghahramani@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences, Shiraz, Iran
Full name of responsible person
Mohammad Mehdi Hosseini, MD
Position
Fellowship of Endourology and Associate Professor of Urology
Other areas of specialty/work
Street address
Endourology ward, Urology Department, Shiraz University of Medical Sciences Shiraz,Iran
City
Shiraz
Postal code
Phone
+98 71 1230 6972
Fax
Email
mmhosseini@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Colorectal Research Center, Shiraz university of medical sciences, Shiraz, Iran
Full name of responsible person
Leila Ghahramani, MD
Position
Colorectal flowship-assistant professor of surgery
Other areas of specialty/work
Street address
Colorectal Research Center, Faghihi hospital, Shiraz, Iran
City
Shiraz
Postal code
Phone
+98 71 1230 6972
Fax
Email
leila_ghahramani@yahoo.com
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