

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of The Efficacy Of DDAVP, Tramadol and Indomethacin in Alleviating the Pain In Patients With Acute Renal Colic

Protocol summary

Summary

Objective: Present study was designed to compare the efficacy of tramadol, desmopressin and indomethacin which are out-patiently prescribed in relieving the pain of renal colic caused by urolithiasis. Study design: This prospective, clinical, randomized trial was conducted in 120 patients (70 men and 50 women, mean age 38.2 years) referring to the emergency room with the renal colic caused by lithiasis without any previous treatment. Inclusion criteria: 120 patients referring to emergency room with renal colic caused by lithiasis without any previous treatment. Exclusion criteria: Patients with evidence of high blood pressure, coronary disease, rhinitis, influenza, anticoagulant therapy, and peptic ulcer, renal or liver failure were excluded from the study, as were any pregnant women. Interventions: In this clinical trial, 120 patients were randomly assigned to three groups: group A, received tramadol 50mg intramuscularly, group B, desmopressin 40 microgram intranasally and patients in group C received , indomethacin 100mg rectally for alleviating the pain. The pain was assessed by written form of VAS scale both on the admission and 30 minutes after therapy administration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030919470N18**
Registration date: **2015-03-14, 1393/12/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-14, 1393/12/23

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2005-06-01, 1384/03/11

Expected recruitment end date

2006-06-01, 1385/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Efficacy Of DDAVP, Tramadol and Indomethacin in Alleviating the Pain In Patients With Acute Renal Colic

Public title

The Efficacy Of DDAVP, Tramadol and Indomethacin in Alleviating the Pain In Acute Renal Colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:120 patients (70 men and 50 women, mean age 38.2 years) referring to emergency room with renal colic caused by lithiasis without any previous

treatment. exclusion criteria: Patients with evidence of high blood pressure, coronary disease, rhinitis, influenza, anticoagulant therapy, peptic ulcer, renal or liver failure were excluded from the study, as were any pregnant women.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code**Approval date**

2005-09-23, 1384/07/01

Ethics committee reference number

cp-p-8411-6410

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

Acute Renal Colic

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

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

To investigate the amount of pain after tramadol 50mg intramuscular in acute renal colic

Timepoint

on the admission and 30 minutes after therapy administration

Method of measurement

VAS scale

2**Description**

To investigate the amount of pain after desmopressin 40 microgram intranasally in acute renal colic

Timepoint

on the admission and 30 minutes after therapy administration

Method of measurement

VAS scale

3**Description**

To investigate the amount of pain indomethacin 100mg rectally in acute renal colic

Timepoint

on the admission and 30 minutes after therapy administration

Method of measurement

VAS scale

Secondary outcomes

empty

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

Patients in group A, received tramadol 50mg intramuscularly for alleviating the pain

Category

Treatment - Drugs

2**Description**

Patients in group B, received desmopressin 40 microgram intranasally for alleviating the pain

Category

Treatment - Drugs

3**Description**

Patients in group C, received indomethacin 100mg rectally for alleviating the pain

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Alireza Aminsharifi

Street address

Zand Street, Faghihi Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Alireza Aminsharifi

Position

Associate professor of Department of Urology/Urologist

Other areas of specialty/work

Street address

Department of Urology, Faghihi Hospital, Zand Street

City

Shiraz

Postal code

Phone

+98 71 3233 0724

Fax

Email

aminsharifi_ar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Alireza Aminsharifi

Position

Associate professor of Department of Urology/Urologist

Other areas of specialty/work

Street address

Department of Urology, Faghihi Hospital, Zand Street

City

Shiraz

Postal code

Phone

+98 71 3233 0724

Fax

Email

aminsharifi_ar@yahoo.com

Web page address

Person responsible for updating data

Contact

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