

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The Efficacy of intranasal desmopressin with Intramuscular sodium diclofenac in comparison with Intramuscular sodium diclofenac alone in acute renal colic

Protocol summary

Summary

Pain is the most common presenting complaint in patients who present to the Emergency Department (ED). Renal colic pain is probably the worst excruciatingly painful event a person can endure. It has been suggested that desmopressin helps to relieve the pain of renal colic immediately. Because of low cost, ease of administration and low adverse effects of desmopressin comparison with opioids and NSAIDs, this study was conducted. The patients 18-55 years old with clinical diagnosis of renal colic were included. The presence of the nephrolithiasis had been approved in all patients in the past or confirmed in later follow up. In a double-blind, clinical trial in the ED of Imam Khomeini Hospital, Ahvaz, Iran, if patients had no exclusion criteria were randomly divided into two different treatment groups (n=120, 60 in each group). Group A received 40 µg of intranasal desmopressin, equal to 4 puffs of available products, combined with 75 mg intramuscular sodium diclofenac. Group B received 75 mg intramuscular sodium with 4 puff of intranasal placebo spray. A visual analog scale (VAS) score from 0-10, at baseline, 15, 30, 45 and 60 minutes of drug administration was utilized to assess the severity of pain. At 30 min, morphin sulfate 5 mg was injected if pain score ≥ 5 . Ultimately at 60 min, morphine sulfate 5 mg intravenously injected again if any degree of pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809082782N1**
Registration date: **2014-06-06, 1393/03/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-06, 1393/03/16

Registrant information

Name

Kambiz Masoumi

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 1222 9166

Email address

kami_masoumi@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-05-16, 1393/02/26

Expected recruitment end date

2014-07-01, 1393/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of intranasal desmopressin with Intramuscular sodium diclofenac in comparison with Intramuscular sodium diclofenac alone in acute renal colic

Public title

Intranasal Desmopressin spray efficacy in acute renal

colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-55 years old ; clinical diagnosis of acute renal colic Exclusion criteria: hypertension ; coronary artery disease ; rhinitis ; influenza ; coagulopathy ; anticoagulant therapy ; peptic ulcer disease ; asthma, kidney failure ; liver failure ; pregnancy ; use of analgesics within 4 hours and Alpha blockers before admission ; addiction to drugs ; surgery on the kidney or ureter ; and fluids therapy immediately before admission ; unbearable pain ; refusal of patients of any cause

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

It & research assistance centre, University complex

City

Ahvaz

Postal code

Approval date

2011-10-01, 1390/07/09

Ethics committee reference number

ETH-359

Health conditions studied

1

Description of health condition studied

renal colic

ICD-10 code

N23

ICD-10 code description

Primary outcomes

1

Description

Pain severity score

Timepoint

Before intervention and at 15, 30, 45 and 60 minutes after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

40 microgram Desmopressin spray intranasal (4 puff)l with 75 mg sodium diclofenac intramuscular

Category

Treatment - Drugs

2

Description

75 mg sodium diclofenac intramuscular with 4 puff NACL 0.65% intranasal spary

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Kambiz Masoumi

Street address

Emergency Department, Imam Khomeini Hospital, Azadegan Ave

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Nader Saki, Deputy of research in university

Street address

IT & research centre, University complex

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Kambiz Masoumi

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work**Street address**

Department of Emergency Medicine, Imam Khomeini Hospital, Azadegan Ave

City

Ahvaz

Postal code

6193673166

Phone

+98 61 1222 9166

Fax**Email**

kami_masoumi@ajums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Kambiz Masoumi

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work**Street address**

Department of Emergency Medicine, Imam Khomeini Hospital, Azadegan Ave

City

Ahvaz

Postal code

6193673166

Phone

+98 61 1222 1965

Fax**Email**

kami_masoumi@ajums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Kambiz Masoumi

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work**Street address**

Department of Emergency Medicine, Imam Khomeini Hospital, Azadegan Ave

City

Ahvaz

Postal code

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Phone

+98 61 1222 1965

Fax**Email**

kami_masoumi@ajums.ac.ir

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