

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of efficacy comparison of intranasal desmopressin vs.intravenous ketorolac in patients with renal colic referring to emergency department

Protocol summary

Summary

(1) Objectives: Comparison of intranasal desmopressin and Intravenous Ketorolac for pain management in renal colic patients (2) Design: Double-blind randomized clinical trial (3) Setting and conduct: 40 patients randomly divided to 2 groups. One group receiving intranasal desmopressin and intravenous normal saline and in other group, intravenous ketorolac and intranasal normal saline was administered. (4) Participants: 16-50 years old patients with renal colic referring to emergency department without history of sensitivity to desmopressin and ketorolac, history of cardiac disease, hypertension, pregnancy and breast feeding, analgesic consumption within 4 hours of admission (5) Intervention: 40 micro grams intranasal desmopressin and 1cc intravenous normal saline have been given to desmopressin group and 30mg intravenous ketorolac and 4 puffs of nasal normal saline was given to ketorolac group. (6) Main outcome measures: Pain score was assessed with visual analogue scale prior to drug administration and 10, 30 and 60 minutes after that

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040527235N1**
Registration date: **2016-10-23, 1395/08/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-23, 1395/08/02

Registrant information

Name

Kambiz Nasiri

Name of organization / entity

Shahid Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti Medical University

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of efficacy comparison of intranasal desmopressin vs.intravenous ketorolac in patients with renal colic referring to emergency department

Public title

Desmopressin effect on pain management of kidney stone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with impression of renal colic; 16-50 years old Exclusion criteria:History of sensitivity to

desmopressin and ketorolac; history of cardiac disease; hypertension; analgesic consumption within 4 hours of admission; pregnancy; breast feeding; hepatic or renal failure

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization using table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Vice chancellor for research, Shahid Beheshti University of Medical Sciences, Velenjak Street

City

Tehran

Postal code

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

lr.sbm.u.msp.rec.1395.79

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, 10,30,60 minutes after intervention

Method of measurement

Pain score based on visual analogue scale

Secondary outcomes

1

Description

Side effects

Timepoint

from starting drug administration until 1 hours after

Method of measurement

Serial physical exam

Intervention groups

1

Description

Intervention group: 40 micro grams intranasal desmopressin and 1 cc intravenous normal saline were administered once.

Category

Treatment - Drugs

2

Description

Control group: 30mg IV ketorolac and 4 puff of intranasal normal saline were administered once.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Hospital

Full name of responsible person

Kambiz Nasiri

Street address

Shahid Madani Street

City

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2

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Kambiz Nasiri

Street address

Qazvin Street

City

Tehran

3**Recruitment center****Name of recruitment center**

Shohada Tajrish Hospital

Full name of responsible person

Kambiz Nasiri

Street address

Shahrdari Street

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research shahid Beheshti university of medical science

Full name of responsible person

Seyed Ali Ziyayi

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Vice chancellor for research, 3rd floor, Medical School, Shahid Beheshti University of Medical Sciences, Velenjak, Tehran, Iran

City

Tehran

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 shahid Beheshti university of medical science

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Emergency Medicine Resident

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Full name of responsible person

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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