Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Randomized clinical trial of Dexmedetomidine efficacy on acute renal colic in comparison with Ketorolac presenting to the emergency department

Protocol summary

Summary

The purpose of this study is to assess the analgesic efficacy of Dexmedetomidine (IV) comparing with Ketorolac (IV) on patients with renal colic diagnosis in the intensity of pain using a visual pain analogue scale (VPAS), a four-grade (five points) pain intensity (PI) scale and a pain-relief scale. 160 patients with confirmed renal colic and Pain score < 3 will be selected. In this active-controlled, double-centre, randomized, single-blind study, the patients will be blinded about Receiving Drug and Active allocation. Patients will be randomized into two groups; Dexmedetomidine group and Ketorolac group. The primary endpoint is the evaluation of the sedative effect of Dexmedetomidine during a 1-h study period, to confirm that Dexmedetomidine abolished or significantly decreased the intensity of pain in renal colic in comparison with Ketorolac. The painkilling effect was defined as a decrease by at least half in the PI scale, and/or a ≥40% decrease in the VAS 20, 40, and 60 min after the first injection of Dexmedetomidine or Ketorolac.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120625402N1**
Registration date: **2015-12-17, 1394/09/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-17, 1394/09/26

Registrant information

Name

Ali Delirrooyfard

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3079

Email address

mosaffa.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of Dexmedetomidine efficacy on acute renal colic in comparison with Ketorolac presenting to the emergency department

Public title

The Effect of Dexmedetomidine on renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: typical physical complaints; a pain intensity between 3 to 10 on a 10 cm visual analogue scale (VAS) marked by the patient; a ureteric or kidney stone verified by ultrasonography and/or native abdominal X-ray; informed consent by the patient; and in women of fertile age, the apparent use of efficient contraception Exclusion criteria: Age<18 y/o and age > 55y/o; Pain score < 3; Pian killer during 6 hours befor ED

arrival; Addiction; Sensitivity to opioides or NSAIDs; Sensitivity to opioides or NSAIDs; SBP<90 mmHg; Abdominal tenderness and rebound; Body temperature>38 °C; History or documents suggesting cardiac, liver, respiratory or renal diseases; History of GIB or active GI ulcer; History of seizure; History of metabolic Disorder; Pregnancy; Suspicious abdominal aortic aneurism or dissection; Inability to speech

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **160**

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
Ethics Committee, Ahvaz Jundishapur University of Medical Sciences

Street address
I.R.Iran - Awz, Mailbox: 159

City
Ahvaz

Postal code
6135715794

Approval date
2015-07-25, 1394/05/03

Ethics committee reference number
IR.ajums.rec.1394.430

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
Duration and intensity of pain in renal colic

Timepoint
Baseline

Method of measurement
visual analogue pain scale (VPAS)

Secondary outcomes

1

Description
Decrease in duration and intensity of pain in renal colic

Timepoint
20, 40, and 60 min after the first injection

Method of measurement
visual analogue pain scale (VPAS)

Intervention groups

1

Description
Intervention Group: Receiving intravenous Dexmedetomidine (200mcg/ml vials) with a dose of 1 gram in 100 ml normal saline during 10 minutes (a 1-h study period, Time Frame: 20 minutes interval) and measuring the pain intensity (PI) in the VAS and adverse events

Category
Treatment - Drugs

2

Description
Control Group: Receiving intravenous Ketorolac (30 mg /ml vials) with a dose of 1 gram in 100 ml normal saline during 10 minutes (a 1-h study period, Time Frame: 20 minutes interval) and measuring the pain intensity (PI) in the VAS and adverse events

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital- Ahvaz

Full name of responsible person
Dr. Ali Delirrooyfard

Street address

City

Ahvaz

2

Recruitment center

Name of recruitment center

Golestan Hospital- Ahvaz

Full name of responsible person

Dr. Ali Delirrooyfard

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Ali Delirrooyfard

Street address

Imam Khomeini Hospital- Ahvaz, Azadegan Avenue, Ahvaz, Iran

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

Dr. Mozhdeh Mosaffa

Position

MD, Resident of Emergency Medicine

Other areas of specialty/work

Street address

Imam Khomeini Hospital- Ahvaz, Azadegan Avenue, Ahvaz, Iran

City

Ahvaz

Postal code

Phone

+98 61 3374 3079

Fax

Email

mosaffa.m@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

Dr. Ali Delirrooyfard

Position

Assistant Professor

Other areas of specialty/work

Street address

Department of Emergency Medicine, Imam Khomeini Hospital- Ahvaz, Azadegan Avenue, Ahvaz, Iran

City

Ahvaz

Postal code

Phone

+98 61 3374 3079

Fax

Email

delirrooyfard-a@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

Dr. Ali Delirrooyfard

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

Street address

Imam Khomeini Hospital- Ahvaz, Azadegan Avenue, Ahvaz, Iran

City

Ahvaz

Postal code

Phone

+98 61 3374 3079

Fax

Email

delirrooyfard-a@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