

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Intravascular dexamethasone plus ketorolac compare with ketorolac alone for treatment of acute renal colic: a randomized clinical trial

Protocol summary

Study aim

Dexamethasone plus Ketorolac compare with the Ketorolac alone for the treatment of acute renal colic

Design

A permuted block randomization, triple blind and controlled clinical trial, for evaluating anti analgesic effects in renal colic in two groups (60 patients in each group).

Settings and conduct

renal colic patients who admitted to the emergency unit of Imam Ali hospital, Bojnurd, randomly admitted to control or intervention groups. They will ask to complete analgesic questionnaire before, 30 and 60 minute after receiving drugs. The study is blinded for both patient and doctor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-60 year old; Renal colic with severity >5 according visual analogue scale-10 cm. Non-inclusion criteria: Pregnancy; Lactation; Contraindications for the use of ketorolac(hypersensitivity to aspirin, other nonsteroidal anti-inflammatory drugs, active or history of peptic ulcer disease, recent or history of GI bleeding or perforation or suspected or confirmed cerebrovascular bleeding, advanced hepatic or renal disease or patients at risk for renal failure (CrCl<30 ml/min), hyperkalemia, and severe heart failure; Contraindications for the use of dexamethasone such as (hypersensitivity , systemic fungal infections, liver failure); Analgesic therapy during 6 hours before admitted to the emergency unit; History of diathesis; Near history of addiction or methadone use; Use of warfarin; Acute abdomen (Peritonitis); axillary temperature >37.7; BP>=18/10 cmHg

Intervention groups

Control group: Ketorolac (30 mg, SD, IV) plus Placebo (D.W, 1 CC, IV), Intervention group : Ketorolac (30 mg, SD, IV) plus Dexamethasone (8 mg, SD, IV),

Main outcome variables

Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044653N1**

Registration date: **2019-09-24, 1398/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-24, 1398/07/02**

Update count: **0**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Maryam Rameshrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7182

Email address

mrameshrad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravascular dexamethasone plus ketorolac compare with ketorolac alone for treatment of acute renal colic: a randomized clinical trial

Public title

Dexamethasone in treatment of acute renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-60 year old, Renal colic with severity more than 5, according to the visual analogue scale-10 cm.

Exclusion criteria:

Pregnancy Lactation Contraindications for the use of ketorolac such as: Hypersensitivity to aspirin, other NSAIDs; active or history of peptic ulcer disease; recent or history of GI bleeding or perforation or suspected or confirmed cerebrovascular bleeding, advanced hepatic or renal disease or patients at risk for renal failure (CrCl<30 ml/min), hyperkalemia, uncontrolled severe heart failure, Contraindications for use of dexamethasone such as: Hypersensitivity , systemic fungal infections, liver failure. Analgesic therapy during 6 hours before admitted to the emergency unit Near history of diathesis Addiction or recently methadone use Use of warfarin Acute abdomen (Peritonitis) Axillary temperature >37.7 BP>=18/10 cmHg,

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the result of randomization by Permuted Block Randomization and individually with R software , patients are allocated to groups sequentially. Drugs in prefilled syringes with unmeaning code for doctor will be introduced to him. Both patient and doctor are blinded about the allocation and the composition of the drugs.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Drugs (ketorolac plus placebo OR ketorolac plus dexamethason) are administrated via prefilled and separated syringes with no details. Doctors, patients and analyzer don't know which groups the patients are. Two groups are nominated A or B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of North Khorasan University of Medical Sciences

Street address

Shahriar

City

Bojnurd

Province

North Khorasan

Postal code

9414974877

Approval date

2019-08-24, 1398/06/02

Ethics committee reference number

IR.NKUMS.REC.1398.047

Health conditions studied

1

Description of health condition studied

colic

ICD-10 code

R10.83

ICD-10 code description

Colic

Primary outcomes

1

Description

Pain severity

Timepoint

Before drug therapy and 30 and 60 min after drug therapy

Method of measurement

Visual analogue scales

Secondary outcomes

1

Description

Grade of vomiting

Timepoint

Before drug therapy and 60 min after drug therapy administration of drugs

Method of measurement

Evaluating the grade of vomiting based on checklist of "W.H., Handbook for Reporting Results of Cancer Treatment. 1979, World Health Organization: Geneva, Switzerland. 1979, World Health Organization: Geneva,

Switzerland".

Intervention groups

1

Description

Intervention group: Ketorolac (30mg/1ml), produced in Iran (30 mg, single dose, intravenous) plus Dexamethasone (8mg/2ml), produced in Iran (8 mg, single dose, intravenous)

Category

Treatment - Drugs

2

Description

Control group: Ketorolac (30mg/1ml), produced in Iran, (30 mg, single dose, intravenous) plus sterile distilled water for injection, produced in Iran (1ml, single dose, intravenous)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency unit of Emem Ali hospital, Bojnourd

Full name of responsible person

Dr Abdolah Razi

Street address

Shahriar

City

Bojnurd

Province

North Khorasan

Postal code

9414974877

Phone

+98 58 3229 7182

Fax

+98 58 3229 7182

Email

abdolahrazi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr Kaveh Hojat

Street address

Shahriar

City

Bojnurd

Province

North Khorasan

Postal code

9414974877

Phone

+98 21 3229 7182

Fax

+98 21 3229 7182

Email

mrameshrad@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bojnourd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr Abdolah Razi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Shahriar

City

Bojnurd

Province

North Khorasan

Postal code

9414974877

Phone

+98 58 3229 7182

Fax

+98 58 3229 7182

Email

abdolahrazi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr Abdollah Razi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Shahriar

City

Bojnurd

Province

North Khorasan

Postal code

9414974877

Phone

+98 58 3229 7182

Fax

+98 58 3229 7182

Email

abdollahrazi@gmail.com

Shahriar street

City

Bojnurd

Province

North Khorasan

Postal code

9414974877

Phone

+98 58 3229 7182

Fax

+98 58 3229 7182

Email

rameshrm2@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Bojnourd University of Medical Sciences

Full name of responsible person

Maryam Rameshrad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address