

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Dec 2023

### 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

rameshradm@mums.ac.ir

##### 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 analyster

#### 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 vometting

#### 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

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##### Province

North Khorasan

##### Postal code

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##### Phone

+98 58 3229 7182

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##### 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

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##### 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

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## 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

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**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**