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 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 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, Bojnurd
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 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 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
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