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 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
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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

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Shahriar

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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
**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

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1

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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