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**
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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 vometing

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
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Full name of responsible person
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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