Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of metoclopramide and ondansetron in the treatment of nausea and vomiting in patients with Renal colic

Protocol summary

Summary

Objective: Compare the efficacy of metoclopramide and ondansetron in the treatment of nausea and vomiting in patients with renal colic. Design and setting: a randomized, double-blind, clinical trial study, single center, clinical trial phase 3. In this study, 180 samples were selected and allocated into two intervention and control groups using block randomization method during 18 months. Inclusion criteria: Renal colic patients with nausea and vomiting; ASA I or II; Age between 18 to 80 years old. Exclusion criteria: Unstable hemodynamic; recent use of antiemetic drugs; allergy to Metoclopramide and Ondansetron. Intervention: All patients received 5 mg Morphine intravenously (IV) and 30 mg ketorolac intramuscularly to reduce pain. Control group received 10 mg metoclopramide, single dose intravenously. Intervention group received 4 mg ondansetron, single dose intravenously. Main outcome measures: 1) Nausea severity assessment at 0 and 30 minutes after the drug injection using visual analogue scale, 2) Number of vomiting episodes from 30 minutes before until 30 minutes after drug injection, 3) Vital signs check at 0 and 30 minutes after injection, 4) Need for excessive drug to reduce nausea and vomiting 30 minutes after injection g, 5) Adverse effects of drugs

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091023552N9**
Registration date: **2016-10-01, 1395/07/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-01, 1395/07/10

Registrant information

Name
Abolfazl Jokar

Name of organization / entity
Arak University of Medical Sceinces

Country
Iran (Islamic Republic of)

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+98 86 3313 2134

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dr.a.jokar@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Arak University of Medical Sciences

Expected recruitment start date

2015-09-13, 1394/06/22

Expected recruitment end date

2016-08-12, 1395/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of metoclopramide and ondansetron in the treatment of nausea and vomiting in patients with Renal colic

Public title

Comparison of metoclopramide and ondansetron on nausea and vomiting in renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Renal colic patients with nausea and vomiting; ASA I or II; age between 18 to 80 years old;

Patients satisfaction on participation in the study. Exclusion criteria: Systolic blood pressure lower than 90 mmHg; Unstable hemodynamic; Opium addiction; history of uncontrolled diseases (Parkinson, Restlessness syndrome, Epilepsy, GI bleeding, Pheochromocytoma); Recent use of CNS depressant drugs; Recent use of antiemetic drugs; allergy to the drugs used in this study

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study the randomization was conducted with block randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City
Arak

Postal code

Approval date
2015-08-24, 1394/06/02

Ethics committee reference number
IR.ARAKMU.REC.1394.158

Health conditions studied

1

Description of health condition studied
Renal colic

ICD-10 code
N23

ICD-10 code description
Unspecified renal colic

2

Description of health condition studied
Nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Nausea severity

Timepoint
0 and 30 minutes after injection

Method of measurement
visual analogue scale

2

Description
Number of vomiting

Timepoint
from 30 minutes before until 30 minute after injection

Method of measurement
questionnaire

Secondary outcomes

1

Description
blood pressure

Timepoint
0 and 30 minutes after injection

Method of measurement
sphygmomanometer

2

Description
Pulse rate

Timepoint
0 and 30 minutes after injection

Method of measurement
pulse rate in 1 minute

3

Description
Respiratory rate

Timepoint
0 and 30 minutes after injection

Method of measurement
Respiratory rate in 1 minute

4

Description
Body Tempreture
Timepoint
0 and 30 minutes after injection
Method of measurement
Thermometer

5

Description
Need to excessive drugs
Timepoint
30 minutes after injection
Method of measurement
Observation

Intervention groups

1

Description
Control: These patients receive 10 milligram metoclopramide(made in Osvah Pharmaceutical Company in Islamic Republic Of Iran) single dose, intravenously.
Category
Treatment - Drugs

2

Description
Intervention: These patients receive 4 milligram ondansetron(made in Shahredaru Pharmaceutical Company in Islamic Republic Of Iran) single dose, intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr hospital
Full name of responsible person
Abolfazl Jokar
Street address
Vali-e-Asr hospital, Vali-e-Asr square, Arak,Iran
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Rafiee
Street address
Arak University of Medical Sciences, Basij Square, Arak, Iran
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Vali-e-Asr hospital
Full name of responsible person
Dr Abolfazl Jokar
Position
Emergency medicine specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty