

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 2134

Email address

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 Temperature

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

Contact

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Position

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Other areas of specialty/work

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Sharing plan

Person responsible for updating data

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Full name of responsible person
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Position
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Other areas of specialty/work
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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