

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of drug combination (morphine-granisetron) with (morphine-placebo) in patients with kidney stones for the control of pain and nausea and vomiting

Protocol summary

Study aim

Comparative study of drug combination (morphine-granisetron) with (morphine-placebo) in patients with kidney stones for the control of pain and nausea and vomiting

Design

The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 60.

Settings and conduct

In this research, all patients referred to the Emergency Department of Hazrat Rasoul Akram Hospital, who suffered from renal colic will be enrolled. Patients will be randomly divided into two groups based on 10 blocks. A total of 120 patients will be examined. Patients and data analyzers will be blind.

Participants/Inclusion and exclusion criteria

All patients referred to the Emergency Department of Hazrat Rasoul Akram Hospital, who suffered from renal colic will be enrolled. Inclusion criteria: age over 16 years old; emergency medicine specialist diagnoses renal colic; no history of allergy to granisetron if mentioned by the patient or a partner; possibility of getting IV Line. Exclusion criteria: patients under the 16 years old; patient unwillingness to continue treatment and follow-up.

Intervention groups

In intervention group: 0.1 mg / kg morphine sulfate intravenously, simultaneously, patients will receive a 5 cc syringe containing 40 mg / kg of intravenous granisetron. In control group 0.1 mg / kg morphine sulfate intravenously, at the same time patients will receive a 5 cc syringe containing saline.

Main outcome variables

Severity of pain; severity of nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170105031787N4**

Registration date: **2019-08-18, 1398/05/27**

Registration timing: **prospective**

Last update: **2019-08-18, 1398/05/27**

Update count: **0**

Registration date

2019-08-18, 1398/05/27

Registrant information

Name

Mohammad-Reza Yasinzadeh

Name of organization / entity

Iran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 5327

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-16, 1398/06/25

Expected recruitment end date

2019-12-16, 1398/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of drug combination (morphine-granisetron) with (morphine-placebo) in patients with kidney stones for the control of pain and nausea and vomiting

Public title

Evaluation of drugs combination in patients with kidney stones

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Emergency medicine specialist diagnoses renal colic No history of allergy to granisetron if mentioned by the patient or a partner Possibility of getting IV Line

Exclusion criteria:

Patient unwillingness to continue treatment and follow-up Age under 16 years

Age

From **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 10 person. In each block, 5 individuals will be in intervention group and 5 will be in control group. A total of 12 blocks will be considered for sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Data will be analyzed by person who is blind to study groups, and patients will also be unaware of the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shahid Hemmat highway, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.IUMS.REC.1397.1191

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

Severity of pain

Timepoint

At the beginning of the injection, half an hour and one hour after the injection

Method of measurement

Visual Analogue Score

2

Description

Severity of nausea

Timepoint

At the beginning of the injection, half an hour and one hour after the injection

Method of measurement

Based on the patient's statement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 0.1 mg / kg morphine sulfate

intravenously, Simultaneously, Patients will receive a 5 cc syringe containing 40 mg / kg of intravenous granisetron

Category

Treatment - Drugs

2

Description

Control group: 0.1 mg / kg morphine sulfate intravenously, at the same time patients will receive a 5 cc syringe containing saline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-Akram Hospital

Full name of responsible person

Mohammad-Reza Yasinzadeh

Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakooti

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mohammad-Reza Yasinzadeh

Position

Assistant Professor of Emergency Medicine

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Full name of responsible person
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Postal code

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