

# 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

yasinzadeh.mr@iums.ac.ir

##### 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

**City**

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**Fax****Email**

yasinzadeh.mr@iums.ac.ir

**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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Shahid Hemmat highway, Tehran,Iran.

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research@iums.ac.ir

**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****Contact****Name of organization / entity**

Iran University of Medical Sciences

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## Person responsible for updating data

### 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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Tehran  
**Province**  
Tehran  
**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