

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Compression the analgesic effect of metoclopramide and ondansetron in renal colic

Protocol summary

Study aim

Compression the analgesic effect of metoclopramide and ondansetron in renal colic

Design

A randomized, blinded clinical trial with a parallel group design of 150 patients, enrolled in 3 groups.

Settings and conduct

Patients referred to emergency department of Shahid Sadoughi and Shahid Rahnemoon hospitals of Yazd. Patients are blind about the type of treatment. In the normal control group, the saline is given as a placebo. The physician is also blind about the type of treatment and the coded drugs will be given to them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of renal stone by sonography
Age between 18 to 55 years
Exclusion criteria:
Complicated renal stone such as pyelonephritis
Oral or intravenous drug administration in 6 hours before refer to hospital
Addiction
Pregnancy
Chronic renal or liver disease
Bilateral stone
Drug allergy

Intervention groups

The participants will be randomly divided into groups A, B and C. Group A were treated with 0.1 mg/kg intravenous morphine and 0.075 mg/kg ondansetron, group B were treated with intravenous morphine at the same dose and 0.15 mg/kg metoclopramide. In group C, patients will be treated with 0.1 mg/kg intravenous morphine plus 5 cc normal saline.

Main outcome variables

Analgesic effect of drugs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130107012050N3**

Registration date: **2020-06-01, 1399/03/12**

Registration timing: **retrospective**

Last update: **2020-06-01, 1399/03/12**

Update count: **0**

Registration date

2020-06-01, 1399/03/12

Registrant information

Name

Mohamadali Jafari Nodushan

Name of organization / entity

Shahid Sadoughi University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1828 4313

Email address

malijafari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compression the analgesic effect of metoclopramide and ondansetron in renal colic

Public title

Compression the analgesic effect of metoclopramide and ondansetron

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of renal stone by sonography Age between 18 to 55 years

Exclusion criteria:

Complicated renal stone such as pyelonephritis Oral or intravenous drug administration in 6 hours before refer to hospital Addiction Pregnancy Chronic renal or liver disease Bilateral stone Drug allergy

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided so that the researcher has no involvement in it using randomized blocks with block size 4 (using a table of random displacements). The type of treatment include morphine and ondasetrone, morphine and metoclopramide and morphine and normal saline is assigned by an out-of-study person according to a randomized list and according to the codes corresponding to each patient who enters the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are blind about the type of treatment. In the normal control group, the saline is given as a placebo. The physician is also blind about the type of treatment and the coded drugs will be given to them.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi of medical sciences

Street address

Bahonar square

City

Yazd

Province

Yazd

Postal code

8915896346

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.274

Health conditions studied**1****Description of health condition studied**

Renal colic

ICD-10 code

K80

ICD-10 code description

Cholelithiasis

Primary outcomes**1****Description**

Pain control

Timepoint

On arrival, 15 minutes, 30 minutes, 1 and 2 hours after drug administration

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes**1****Description**

Nausea control

Timepoint

On arrival, 15 minutes, 30 minutes, 1 and 2 hours after drug administration

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group 1: In this group 0.1 mg/kg intravenous morphine sulfate from Exir_Iran company and 0.075 mg/kg ondansetron from Tehran daru will be injected once.

Category

Treatment - Drugs

2**Description**

Intervention group 2: In this group 0.1 mg/kg intravenous

morphine sulfate from Exir_Iran company and 0.15 mg/kg metoclopramide from Tehran daru will be injected once.

Category

Treatment - Drugs

3**Description**

Control group: In this group 0.1 mg/kg intravenous morphine sulfate from Exir_Iran company plus 5 cc normal saline will be injected once

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi hospital

Full name of responsible person

Dr Mohammad Ali Jafari Nodoshan

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2**Recruitment center****Name of recruitment center**

Shahid Rahnemon hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Jafari Nodoshan

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Specialist

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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