

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the analgesic effect of intravenous metoclopramide and morphine in the treatment of acute renal colic, A randomized double-blind trial

Protocol summary

Study aim

Comparison of the analgesic effect of intravenous metoclopramide and morphine in the treatment of acute renal colic

Design

Clinical trial with intervention and control group, with parallel groups, double-blind, randomized using block method, phase three on 68 patients

Settings and conduct

In this study, patients between 18-55 years old who have inclusion criteria are included in the study. Patients are chosen in the emergency room of Golestan hospital in Ahvaz, 17 Shahrivar and Shahid Beheshti hospital in Abadan. Based on the patient's complaint, patient's history, physical examination, and medical records, patients with renal colic have been diagnosed. Patients sign a consent form and then enter the study. The study process is double-blind and the participants, researchers and staff are blinded and treatment protocol are named A and B, are chosen randomly by lottery under researcher and second nurse supervision, patients are divided into two groups of intervention and control groups as permuted block.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients between ages of 18 and 55 who have been diagnosed with renal colic. Exclusion criteria: All patients aged under 18 years and over 55 years; All patients allergic to morphine and metoclopramide All patients who do not want to cooperate for any reason; All patients who do not fill out the consent form; Pregnant patients. Patients with fever over 38 degrees Patients with unstable hemodynamics Patients with heart, kidney, lung and liver defect Use any sedative up to 24 hours before going to the emergency room

Intervention groups

Control group: In control group, pain intensity is

evaluated by visual analogue scale and morphine 0.1 mg/kg with 100 cc normal saline is injected. Intervention group: In the intervention group, intravenous metoclopramide (10mg) is injected.

Main outcome variables

Reduce pain intensity and pain control speed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200505047304N1**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **retrospective**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Taghva Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5335 0950

Email address

taghvafathi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-09-22, 1399/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the analgesic effect of intravenous metoclopramide and morphine in the treatment of acute renal colic, A randomized double-blind trial

Public title
Effect of Metoclopramide on Kidney Stone

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged between 18 and 55 years who have been diagnosed with renal colic
Exclusion criteria:
Patients under 18 years and over 55 years old Patients who are allergic to morphine and metoclopramide Patients who do not want to cooperate after the start of research for any reason (e.g. due to drug complications) Patients who do not fill out the consent form Pregnant Women Patients with a Fever over 38 degrees Unstable hemodynamics Heart, kidney, lung or liver defects Use of any sedative up to 24 hours before going to the emergency room.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
randomization will be done using the site <https://www.sealedenvelope.com/> in two groups A and B in six-digit blocks. This list will be provided to the relevant doctor after printing.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and data analyzers will not be informed of the type of drug (A or B) until the end of the study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Science., Esfand Ave., Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.AJUMS.REC.1398.903

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

Average pain score on visual analogue scale

Timepoint

Measuring the average pain score at the beginning of the study (before starting the intervention) and 15, 30, 45 and 60 minutes after the intervention begins

Method of measurement

VAS (Visual Analogue Scale)

Secondary outcomes

empty

Intervention groups

1

Description

control group: In the control group, the severity of pain is first evaluated by Visual Analogue Scale (VAS) criteria and the morphine 0.1 mg / kg is injected with 100cc

normal saline and the severity of pain based on VAS is evaluated in zero, 15, 30, 45 and 60 minutes. And if in the 30th minute, the patient's pain criterion is based on VAS is more than 5, morphine is injected again for the patient, and if at the end of 60 minutes, the patient's pain is less than 2, the patient is discharged without additional work.

Category

Treatment - Drugs

2

Description

Using visual analog scale, they are assessed for pain intensity after drug injection (worst possible pain = 10 without pain = 0). Patients receive intravenous metoclopramide intervention at a dose of 10 mg. In the 15th minute, the pain is assessed with VAS, which is considered to be significant for greater than or equal to 2. In the 30th minute from the start of treatment, if the pain is more than 5 with VAS, The patient's pain is controlled with morphine. In the 45th and 60th minutes, the patient's pain is examined according to the VAS criteria. If the patient's pain is less than 2 in the 60th minute based on VAS, the patient is discharged from the emergency room without any additional action.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital of Ahvaz

Full name of responsible person

Farshad Fathi

Street address

Farvardin Blvd, Golestan District

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2

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

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End of Khalij Fars Blvd, Shotait District

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3

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Farshad Fahi

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Ahmad Abad Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badoui

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Ahvaz Jundishapur University of Medical Science.,
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Dr.MohammadBedoui@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Taghva Fathi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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