

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the analgesic effect of Magnesium-sulfate and Paracetamol with Paracetamol and Placebo in the treatment of renal colic patients: double-blind clinical trial study

Protocol summary

Study aim

To assess the effect of intravenous Paracetamol and Magnesium-sulfate versus intravenous Paracetamol and placebo on pain relief in patients with renal colic

Design

This is a double-blind randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with Renal colic will refer to Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician and analyzer who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60 years, Renal colic, Minimum score of 5 from the visual analogue scale(VAS) at baseline, Glasgow Coma Scale(GCS) of 15 Exclusion criteria: Unstable vital signs, Pregnancy or any doubt about pregnancy, Use of pain medication during the last 6 hours, Abdominal pain and the possibility of peritonitis, Narcotic addiction, Cardiac arrhythmia, Cardiac, renal or liver failure, Disposal of stone(s), Drug history of calcium channel blockers, History of alcoholism, History of neuromuscular disease and underlying bradycardia (heart rate less than 60) and long QRS interval, History of hypotension, History of hypocalcemia and hypomagnesemia, Barbiturates and general anesthetics use, History of seizures

Intervention groups

Intervention group: Intravenous Paracetamol 15 mg/ kg single dose plus Magnesium-sulfate 50% 15 mg/kg in 100 ml normal saline single dose Control group: Intravenous Paracetamol 15 mg/ kg single dose plus 100 ml normal saline single dose

Main outcome variables

Treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190907044717N1**

Registration date: **2020-04-08, 1399/01/20**

Registration timing: **prospective**

Last update: **2020-04-08, 1399/01/20**

Update count: **0**

Registration date

2020-04-08, 1399/01/20

Registrant information

Name

Parham Torabi navid

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the analgesic effect of Magnesium-sulfate and Paracetamol with Paracetamol and Placebo in the treatment of renal colic patients: double-blind clinical trial study

Public title
Comparison of the analgesic effect of Magnesium-sulfate and Paracetamol with Paracetamol and Placebo in the treatment of renal colic

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Individuals who are clinically suspected of having renal colic or have been diagnosed with ultrasound or CT scan with a definitive diagnosis of renal colic Minimum score of 5 from the visual analogue scale(VAS) at baseline Glasgow Coma Scale(GCS) of 15
Exclusion criteria:
 Body temperature > 38° C Pregnancy or any doubt about pregnancy Use of pain medication during the last 6 hours Abdominal pain and the possibility of peritonitis Not signing the informed consent Unstable clinical conditions and hypotension(systolic pressure less than 90 or 20% of baseline pressure) and bradycardia(less than 60) and respiratory rate lower than 16 Disposal of stone(s) History of heart diseases History of liver diseases History of kidney diseases History of metabolic diseases History of seizures Drug history of calcium channel blockers History of alcoholism History of mental disorders, depression and recent use of sedative or anti-psychotic or antidepressants History of drug abuse and addiction History of neuro-muscular disease and underlying bradycardia (heart rate less than 60) and long QRS interval History of hypotension History of hypocalcemia and hypomagnesemia Barbiturates and general anesthetics use

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this

purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same so that the intervention group will receive serum with the drug while the control group will receive serum without the drug. Both types of serum are colorless and are indistinguishable. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients are apart from the person who gives the drugs to the patients. Thus examiner will not be aware of the intervention. The data will be coded and given to the analyzer. THEREFORE, the analyzer will be unaware of the type of interventions. Thus, the trial will be run as double-blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Hamadan University of Medical Sciences
Street address
 Vice-chancellor for Research and Technology,
 Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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 Hamadan
Province
 Hamadan
Postal code
 6517838695
Approval date
 2019-12-07, 1398/09/16
Ethics committee reference number
 IR.UMSHA.REC.1398.732

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**

The severity of renal colic's pain

Timepoint

Before the intervention and 20, 40, and 60 minutes after the intervention

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

empty

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

Intervention group: Intravenous Paracetamol 15 mg/ kg single dose plus 100 ml normal saline including magnesium sulfate 50% 15 mg/kg as single dose

Category

Treatment - Drugs

2**Description**

Control group: Intravenous Paracetamol 15 mg/ kg single dose plus 100 ml normal saline without any drug as single dose

Category

Treatment - Drugs

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

Besat Hospital in Hamadan city

Full name of responsible person

Parham Torabinavid

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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

Hamedan 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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Parham Torabinavid

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

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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