Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 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 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, 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
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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

City

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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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Sponsors / Funding sources

1

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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

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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