Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of oral ketamine versus placebo on pain relief in patients with renal colic: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of oral ketamine versus placebo on pain relief in patients with renal colic. Design: A double blinded randomized clinical trial. Setting and conduct: The eligible patients with renal colic who will refer to Shahid Beheshti Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) having renal colic; (b) age of 18 to 60 years. Exclusion criteria: (a) having psychological or personality disorder; (b) pregnancy or breastfeeding; (c) having cardiovascular diseases, hypertension, epilepsy, glaucoma, or diabetes. Intervention: Intramuscular injection of pethidine 1 mg/kg to maximum of 100 mg plus a single dose of 5 mg/kg oral ketamine 0.5%. Control: Intramuscular injection of pethidine 1 mg/kg to maximum of 100 mg plus a single dose of 0.1 mg/kg oral glucose 5%. Primary outcome: Severity of pain using Visual Analog Scale before and 3 hours after intervention. Secondary outcome: (a) severity of nausea using Four Point Scale before and 3 hours after intervention; (b) number of vomiting with question before and 3 hours after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410319014N46**
Registration date: **2014-11-01, 1393/08/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-01, 1393/08/10

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-04-26, 1392/02/06

Expected recruitment end date

2013-06-07, 1392/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral ketamine versus placebo on pain relief in patients with renal colic: a double blinded randomized clinical trial

Public title

Effect of oral ketamine versus placebo on pain relief in patients with renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) having renal colic; (b) age of 18 to 60 years. Exclusion criteria: (a) having psychological or personality disorder; (b) pregnancy or breastfeeding; (c)

having cardiovascular diseases, hypertension, epilepsy, glaucoma, or diabetes.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: The patients will be allocated to intervention and control groups through block randomization. For this purpose, patients will be divided into groups of four then each group will be allocated to intervention and control groups 2 by 2. Blinding: The patients in the intervention and control groups will receive drug with the same volume and color. Therefore, they will not aware of the intervention. In addition, the examiner will not aware of the type of intervention. Accordingly, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2014-09-16, 1393/06/25

Ethics committee reference number
D/P/16/35/9/2887

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
before and 3 hours after intervention

Method of measurement
using Visual Analog Scale

Secondary outcomes

1

Description
severity of nausea

Timepoint
before and 3 hours after intervention

Method of measurement
using Four Point Scale

2

Description
number of vomiting

Timepoint
before and 3 hours after intervention

Method of measurement
with question

Intervention groups

1

Description
Intramuscular injection of pethidine 1 mg/kg to maximum of 100 mg plus a single dose of 5 mg/kg oral ketamine 0.5%

Category
Treatment - Drugs

2

Description
Intramuscular injection of pethidine 1 mg/kg to maximum of 100 mg plus a single dose of 0.1 mg/kg oral glucose 5%.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Maedeh Hassani
Street address
Shahid Beheshti Hospital, Eram Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty