

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Name**

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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

Medical student

**Other areas of specialty/work**

**Street address**

Shahid Beheshti Hospital, Eram Ave.

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**Phone**

+81 38380704

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**Email**

msh6440@gmail.com

**Web page address**

## 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

**City**

Hamadan

**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**

Shahid Beheshti Hospital

**Full name of responsible person**

Maedeh Hassani

**Position**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Shahriar Amihassani

**Position**

Urologist

**Other areas of specialty/work**

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shahriar-amirhassani@yahoo.com

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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*