Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of injection of ketamine before surgery to reduce pain after renal surgery

Protocol summary

Study aim
Determining the Effect of Ketamine on pain after open renal stone surgery

Design
Double-blind clinical trial study, simple randomization, 28 patients in each group, phase 1 clinical trial.

Settings and conduct
After obtaining the approval of the Ethics Committee of the Faculty of Medicine and obtaining informed consent from the patients in Imam Reza Hospital and Ghaem Hospital, patients who are candidates for open renal surgery are entered. Patients with age between 18 and 65 years and ASA 1, 2 classes are enrolled in the study and randomly assigned to the control and intervention groups using random software and then using closed envelopes. All patients receive premedication according to the standard protocol of the hospital and pre-mild sedation.

Participants/Inclusion and exclusion criteria
Patients Candidated to Open Kidney surgery are enrolled in the study, and patients with other diseases are excluded.

Intervention groups
Intervention group: ketamine injection (0.5mg / kg) (volume 2 cc) before skin incision Control group (placebo, placebo): normal saline 2 cc before skin incision

Main outcome variables
Duration of surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170429033680N10**
Registration date: **2018-12-03, 1397/09/12**
Registration timing: **registered_while_recruiting**
Last update: **2018-12-03, 1397/09/12**
Update count: **0**

Registration date
2018-12-03, 1397/09/12

Registrant information

Name
Farideh Golhasani

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of injection of ketamine before surgery to reduce pain after renal surgery

Public title
The effect of injection of ketamine before surgery to reduce pain after renal surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-65 years old ASA Class 1, 2 BMI less than 30 Candidate for open kidney surgery Satisfaction to participate in the study
Exclusion criteria:
Sensitivity to the drug being studied Drug and alcohol addiction History of seizure and psychological illness Use of any analgesic drug before surgery

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize, we use a simple random method (random numbers table)

Blinding (investigator's opinion)
Double blinded

Blinding description
Using different enclosed envelopes. patients and researcher were unaware from type of drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical sciences

Street address
Mashhad University of Medical Sciences; International Offic Administration Center(Qoreishi Building) ; Daneshgah St., Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2018-09-06, 1397/06/15

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.280

Health conditions studied

1

Description of health condition studied
kidney diseases

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Taking opioid drugs

Timepoint
Twenty-four hours after surgery

Method of measurement
NVR scale

Secondary outcomes

1

Description
Pain

Timepoint
24 hours after surgery

Method of measurement
vas Scale

Intervention groups

1

Description
Intervention group: Inject ketamine (0.5mg / kg) (2 cc volume) before skin incision

Category
Treatment - Drugs

2

Description
Control group: Prescribe cc 2 normal saline before skin incision

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person

Dr Mohammd Alipour
Street address
Department of Anesthesiology, Imam Reza Hospital, Square Taghiabad, Khorasan Razavi, Mashhad
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Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Alipour
Position
Associated professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Presenting the results as an article
When the data will become available and for how long
After printing the article
To whom data/document is available
researchers
Under which criteria data/document could be used
In order to expand the research
From where data/document is obtainable
Email to Academic Officer
What processes are involved for a request to access data/document
send mail
Comments