

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2631

Email address

golhasanif1@mums.ac.ir

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**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 Mohamm Alipour

Street address

Department of Anesthesiology, Imam Reza Hospital,
Square Taghiabad, Khorasan Razavi, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3801 2612

Email

alipourm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Phone

+98 51 3843 3363

Email

ramresearch@mums.ac.ir

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

Street address

Department of Anesthesiology, Imam Reza (AS)
Hospital, Taghiabad Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 518022711

Email

alipourm@mums.ac.ir

Person responsible for scientific 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

Street address

Imam Reza Hospital, Square Taghiabad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2711

Email

alipourm@mums.ac.ir

Person responsible for updating data

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

Street address

, Imam Reza Hospital, Square Taghiabad, Khorasan Razavi, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2711

Email

alipourm@mums.ac.ir

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