Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of intravenous ketamine before skin incision with acetaminophen before anesthesia on pain after PCNL surgery

Protocol summary

Study aim
Comparison of the effect of preemptive use of both acetaminophen and ketamine in reducing pain after PCNL

Design
This is a double-blind, interventional study with control group. control or intervention group is randomly divided in tow groups. The tow groups will be similar to induction and maintenance of anesthesia.

Settings and conduct
After the approval of the research committee and the Ethics Committee of the Faculty of Medicine and informed consent of patients at Ghaem Hospital and Imam Reza and Mashhad, Central Operations Section, available to patients undergoing PCNL surgery with general anesthesia is selected.

Participants/Inclusion and exclusion criteria
Patients undergoing general anesthesia with PCNL surgery are selected

Intervention groups
Intervention group 1: 0.5 ml / kg injection (2 cc volume) of intravenous ketamine before skin incision + 100 ml normal saline injection in half an hour before anesthesia Intervention group 2: Inject 1000 milligrams of acetaminophen in 100 cc normal saline intravenous half an hour before anesthesia Control group: None of the two above drugs is prescribed.

Main outcome variables
scoring of the NVR score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170429033680N11**
Registration date: **2018-12-27, 1397/10/06**
Registration timing: **registered_while_recruiting**
Last update: **2018-12-27, 1397/10/06**
Update count: **0**

Registration date
2018-12-27, 1397/10/06

Registrant information

Name
Farideh Golhasani

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3802 2631

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golhasanif1@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2019-11-13, 1398/08/22

Actual recruitment start date
2018-11-13, 1397/08/22

Actual recruitment end date
2019-11-13, 1398/08/22

Trial completion date
empty

Scientific title
Comparison of the effects of intravenous ketamine before skin incision with acetaminophen before anesthesia on pain after PCNL surgery

Public title
Comparison of the effects of intravenous ketamine before skin incision with acetaminophen before anesthesia on pain after PCNL surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA class one and two Age between 18 and 70 years No sensitivity to used drugs Lack of hypertension and ischemic heart disease The lack of a known psychiatric illness Ability to speak and understand Persian No drug addiction to alcohol Not taking any analgesic drugs within the last 24 hours

Exclusion criteria:

The creation of surgical complications that make the process turn into action

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **111**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table, there is not allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind study in which subjects under study and the allocation of samples to groups do not know the 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

Daneshgah St, Ghoreish Department .

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.483

Health conditions studied

1

Description of health condition studied

kidney diseases

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

scaling of the NVR score

Timepoint

after surgery

Method of measurement

questionnare

2

Description

pain

Timepoint

after surgery

Method of measurement

VaS score

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Intervention group: inject 1000 milligrams of acetaminophen in 100cc normal saline solution within 15 minutes before skin incision.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad University of Medical

Full name of responsible person
Mohsen Sabermoghaddam

Street address
Imam Reza Hospital, Square Taghiabad

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Masshad

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Razavi Khorasan

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9137913316

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+98 51 3852 5209

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

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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
Mohsen Saber Moghaddam

Position
Associate 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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data file
When the data will become available and for how long
6 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Statistical analyzes are permitted in overview articles on delivered data
From where data/document is obtainable
Send an email to sabermoghaddamm@mums.ac.ir
What processes are involved for a request to access data/document
6 months after publication
Comments