Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of painless effects between ketamin and combinations of different doses of ketamin and bupivacaine after Percutaneous Nephrolithotripsi (PCNL) in patients with renal calculi.

Protocol summary

Summary

This study was done as a controlled randomized clinical trial. The aim of this study was reducing of pain and opium consumption after removing kidney stones through the subcutaneous duct. Fifty patients with 18-75 years old are suffering from kidney stones in self kidney were being randomly divided into 5 groups: The first group received intravenously 2 cc of normal saline (Amp Normal Saline 0.9%, Dena Pharmaceutical Co, Tabriz, Iran). The second group received intravenously 2 cc of bupivacaine 0.5% (Amp bupivacaine hydrochloride 0.5%, Astrazeneca Co, France) and 6 ml of distilled water (Vial 5 cc distilled water, Dena Pharmaceutical Co, Tabriz, Iran). The third group received intravenously 2 cc of bupivacaine 0.5%, 5 ml of distilled water and 1cc of ketamine 5% (Vial Ketamin Hydrochloride 10ml, Rotexmedica Co, Germany). The fourth group received intravenously 2 cc of bupivacaine 0.5%, 5 ml of distilled water and 1cc of ketamine 5%. The fifth group received intravenously ketamine 5%, 1mg/kg at the end of surgery.The pain and narcotic use of patients was been assess and compare between five groups after extubation, leaving the recovery room and at the different hours of ward admission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092612695N1**
Registration date: **2013-10-14, 1392/07/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-14, 1392/07/22

Registrant information

Name
mohammadreza khajavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6312 1220
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Recruitment status

Recruitment complete

Funding source
Deputy of Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of painless effects between ketamin and combinations of different doses of ketamin and bupivacaine after Percutaneous Nephrolithotripsi (PCNL) in patients with renal calculi.

Public title

Comparison of painless effects between ketamin and combination of ketamin and bupivacaine in patient with renal calculi

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- 18-75 years. 2- Presence of calculi only in kidney itself. Exclusion criteria: 1- Drug abuser 2- Pregnancy 3- History of renal disease 4- Serum creatinine level more than 2mg/dl 5- History of uncontrolled Hypertension 6- History of psychological disorders and use of psychoactive drug

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This was a double-blind, 5-arm, parallel-group, placebo-controlled, randomized study. Four groups were consider the experimental treatment under study, while the one group was consider as a control group and was given a placebo. According to a table of random number, the patients were randomized to 1 of the following 5 treatment regimens. In this study, two groups of individuals involved in the trial did not know the identity of the intervention that is given to each participant. These two groups included the participants and the investigators in charge of assessing the outcomes of the interventions

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Central building of Tehran University of Medical sciences, Ghods st, Keshavarz blv.

City
Tehran

Postal code
66524185424

Approval date
2013-04-21, 1392/02/01

Ethics committee reference number
130-461-91-د

Health conditions studied

1

Description of health condition studied
Nephrolithiasis

ICD-10 code
N20.0

ICD-10 code description
Nephrolithiasis NOS

Primary outcomes

1

Description
Pain

Timepoint
5-10-15-30 min after extubation, recovery, 1-6-12-24 hours after the patient has been transferred to the ward.

Method of measurement
Visual Analogue Scale

2

Description
Opioid consumption

Timepoint
Recovery and 24 hour after surgery

Method of measurement
mg

Secondary outcomes

1

Description
Agitation

Timepoint
5-10-15-30 min after extubation, recovery, 1-6-12-24 hours after ward admission

Method of measurement
Richmond Agitation Sedation Scale

Intervention groups

1

Description
1th Intervention:2 cc of bupivacaine 0.5%, 6 ml of distilled water

Category
Treatment - Drugs

2

Description
2th Intervention: 2 cc of bupivacaine 0.5%, 5 ml of

distilled water and 1cc of ketamine 5%

Category

Treatment - Drugs

3

Description

3th Intervention: 2 cc of bupivacaine 0.5%, 5 ml of distilled water and 1cc of ketamine 5%

Category

Treatment - Drugs

4

Description

4th Intervention: ketamine 5%, 1mg/kg

Category

Treatment - Drugs

5

Description

Control: 2 cc of normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Ali Valizadeh

Street address

Sina Hospital, Imam Khomeini St, Hasan Abad Sq

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research,Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research,Tehran 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

Sina Hospital, Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

Anesthesiologist

Other areas of specialty/work

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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