

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of painless effects between ketamin and combinations of different doses of ketamin and bupivacaine after Percutaneous Nephrolithotripsy (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)

##### Phone

+98 21 6312 1220

##### Email address

khajavim@tums.ac.ir

#### 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 Nephrolithotripsy (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**

130-461-91-3

## **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**

Tehran

**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**

**Street address**

Imam khomeni St, Hasan Abad Sq, Sina hospital

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 0000

**Fax**

+98 21 6634 8553

**Email**

KHAGAVIM@TUMS.AC.IR

**Web page address**

**Person responsible for scientific 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**

**Street address**

Imam khomeni St, Hasan Abad Sq, Sina hospital

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 0000

**Fax**

+98 21 6634 8553

**Email**

khajavim@tums.ac.ir

**Web page address**

www.tums.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Sina Hospital, Tehran University of Medical Sciences

**Full name of responsible person**

Ali Valizadeh

**Position**

Anesthesiology assistant

**Other areas of specialty/work****Street address**

Imam khomeni St, Hasan Abad Sq, Sina hospital

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 0000

**Fax**

+98 21 6312 0000

**Email**

alivalizadeh@yahoo.com

**Web page address**

## 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*