# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 2026

## Comparison of analgesic effect of intravenous acetaminophen and ketamine versus intravenous acetaminophen and tramadol in patients undergoing open renal surgeries

## Protocol summary

**Summary**

The purpose of study is comparison of analgesic effect of intravenous acetaminophen and ketamine versus intravenous acetaminophen and tramadol. The study will be done on 60 patients undergo open renal surgeries. The patients will be divided randomly to two groups. At the end of surgery one group will receive intravenous acetaminophen and ketamine, another group intravenous acetaminophen and tramadol. In the purpose of blinding another physician exception the physician who administers the drug will measure the patients. After the patients arriving the recovery room, outcomes which contain severity of pain based on VAS, amount of agitation based on Richmond Sedation Scale will be measured.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201509143773N14**
Registration date: **2016-02-07, 1394/11/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-02-07, 1394/11/18

**Registrant information**

**Name**

Farsad Imani

**Name of organization / entity**

Tehran University of Medical Sciences and Health Services

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 4469 0816

**Email address**

imanifar@sina.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Tehran University of Medical Sciences

**Expected recruitment start date**

2015-10-21, 1394/07/29

**Expected recruitment end date**

2016-10-21, 1395/07/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of analgesic effect of intravenous acetaminophen and ketamine versus intravenous acetaminophen and tramadol in patients undergoing open renal surgeries

**Public title**

Reduction of post-operative pain using intravenous acetaminophen, ketamine and tramadol in open renal surgeries

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Older than 18 years old; With ASA I & II. Exclusion criteria: patients with the history of opium use; history of psychological disorders; chronic low back pain.

**Age**

From **18 years** old to **100 years** old

**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Type of randomization= Block randomization

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Tehran University of Medical Sciences
**Street address**
Ghods cross, Keshavarz Blvd.
**City**
Tehran
**Postal code**
**Approval date**
2015-09-12, 1394/06/21
**Ethics committee reference number**
IR.TUMS.REC.1394.745

## Health conditions studied

### 1

**Description of health condition studied**
post operation pain
**ICD-10 code**
R10.2
**ICD-10 code description**
Pelvic and perineal pain

## Primary outcomes

### 1

**Description**
pain
**Timepoint**
5, 10, and 20 minutes after arriving to the recovery room, to the ward, and also 1 and 6 hours after transfer to the ward.
**Method of measurement**
Visual Analog Scale

### 2

**Description**
level of agitation
**Timepoint**
5, 10, and 20 minutes after arriving to recovery room, time to transfer from recovery to the ward, and also 1 and 6 hours after transfer to the ward.
**Method of measurement**
Richmond Sedation Scale

## Secondary outcomes

### 1

**Description**
Opiom requirment
**Timepoint**
At recovery room and 6 hour after the surgery
**Method of measurement**
Submit file

### 2

**Description**
patient hemodynamic
**Timepoint**
5, 10, 20 minutes after the infusion and at exit the recovery room and 6 hour after the surgery
**Method of measurement**
Blood pressure and pulse rate (Monitoring instrument)

## Intervention groups

### 1

**Description**
First intervention group: intravenous acetaminophen 1gr and tramadol 0.7mg/kg will be administered At the end of surgery.
**Category**
Treatment - Drugs

### 2

**Description**
Second intervention group: intravenous acetaminophen 1gr and ketamine 0.5mg/kg will be administered at the end of surgery .
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Sina hospital

**Full name of responsible person**
Dr Mahdi Saburi

**Street address**
Sina hospital, Hasanabad Sq., Imam Khomeini St.

**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for research,Tehran University of Medical Sciences

**Full name of responsible person**
Dr Mahdi Saburi

**Street address**
Sina hospital, Hasanabad Sq., Imam Khomeini St.

**City**
Tehran

**Grant name**
-

**Grant code / Reference number**
-

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

**Title of funding source**
Vice chancellor for 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**
Tehran University of Medical Sciences

**Full name of responsible person**
Dr Mahdi Saburi

**Position**
Resident

**Other areas of specialty/work**

**Street address**
Sina hospital, Hasanabad Sq., Imam Khomeini St.

**City**
Tehran

**Postal code**

**Phone**
+98 21 63120

**Fax**

**Email**
Pouya.sabouri@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Dr Farsad Imani

**Position**
Professor assistant

**Other areas of specialty/work**

**Street address**
Sina hospital Hasanabad Sq., Imam Khomeini St.

**City**
Tehran

**Postal code**

**Phone**
+98 21 63120

**Fax**

**Email**
imanifar@tums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Dr Mahdi Saburi

**Position**
Resident

**Other areas of specialty/work**

**Street address**
Sina Hospital, Hasanabad Sq., Imam Khomeini St.

**City**
Tehran

**Postal code**

**Phone**
+98 21 63120

**Fax**

**Email**
Pouya.sabouri@gmail.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*