

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)

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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**

Opium requirement

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

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Professor assistant

Other areas of specialty/work

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Person responsible for updating data

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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