Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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

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Sina hospital, Hasanabad Sq., Imam Khomeini St.

City
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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
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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Professor assistant

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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