Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the effects of wound infiltration of combined ketamine and tramadol with solely ketamine and Tramadol on reduction of post-operative pain of pyelolithotomy operation

Protocol summary

Summary

The purpose of study is comparison of the effects of wound infiltration of combined ketamine and tramadol with solely ketamine and Tramadol in patients scheduled pyelolithotomy. Inclusion criteria are scheduled for pyelolithotomy and ASA1-2 and exclusion criteria: Opium addiction; psychologic disease. Study population: patients scheduled pyelolithotomy surgery at Sina hospital. During 1 year, 64 patients over a one-year period will be recruited to 4 groups. One group as control group will receive no drug for prevention of post operative pain. Second group will receive Tramadol, third group Tramadol plus ketamine, forth group ketamine at the edge of the incision of the surgery. At 5/10/15/30 minutes after the exit recovery and 1/3/6/12/24 hours after entrance to the ward pain score will be measured by the visual analogue score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501243773N12**
Registration date: **2015-01-31, 1393/11/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-31, 1393/11/11

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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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-03-19, 1391/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of wound infiltration of combined ketamine and tramadol with solely ketamine and Tramadol on reduction of post-operative pain of pyelolithotomy operation

Public title

Comparison of combined ketamine and tramadol with solely ketamine and Tramadol on reduction of post-operative pain of pyelolithotomy operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients scheduled pyelolithotomy; ASA1-2. exclusion criteria: Opium addiction; Psychologic disease.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences-Research administration

Street address

Keshavarz Bv. Ghods st. Cross

City

Tehran

Postal code

Approval date

2013-09-29, 1392/07/07

Ethics committee reference number

137645-9011174039

Health conditions studied

1

Description of health condition studied

Post operative pain at pelvic region

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes

1

Description

post operative pain

Timepoint

At 5/10/15/30 minutes after the exit recovery and 1/3/6/12/24 hours after entrance to the ward

Method of measurement

visual analogue score

Secondary outcomes

1

Description

agitation / sedation level

Timepoint

5/10/15/30 minutes after the exit recovery

Method of measurement

Richmond Agitation-Sedation Scale

Intervention groups

1

Description

Control group will be received no drug as prevention of post operative pain

Category

Prevention

2

Description

First intervention group: tramadol 0.5% 1 mL

Category

Prevention

3

Description

Second intervention group: tramadol 0.5% 1 mL + ketamine 0.5mg/kg

Category

Prevention

4

Description

Third intervention group: ketamine 0.5mg/kg

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Mohammad Reza Khajavi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Masud Yunesian
Street address
Department of Environmental Health Engineering, School of Public Health
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences and Health Services
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
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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