Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Effect of preemptive subcutaneous infiltration of two doses of tramadol on post-operative pain of urologic surgeries, a double-blinded, randomized, placebo-controlled clinical trial.

Protocol summary

Summary

Through this double-blind, randomized, placebo-controlled trial, the effect of subcutaneous preemptive infiltration of two doses of Tramadol on post-operative pain in urologic surgeries will be evaluated. 96 patients who are candidates for urologic surgeries in Ali-Asghar hospital will be randomly assigned into one of the three groups of the trial. Before the incision, patients will receive 1mg/kg Tramadol in 10 cc normal saline 0/9%, 2mg/kg Tramadol in 10 cc normal saline 0/9%, or 10 cc normal saline 0/9% with subcutaneous infiltration at the location of the incision. Pain, sedation score, nausea, vomiting, pulse rate, respiratory rate, and mean arterial pressure will be assessed 15, 30, and 60 minutes and also 4, 8, 16, and 24 hours after surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804222159N1**
Registration date: **2010-05-29, 1389/03/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

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Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preemptive subcutaneous infiltration of two doses of tramadol on post-operative pain of urologic surgeries, a double-blinded, randomized, placebo-controlled clinical trial.

Public title

Comparative evaluation the effect of preemptive subcutaneous infiltration of two doses of tramadol on post-operative pain of open kidney and urinary tract surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-75 years old, candidates for urologic surgeries with ASA score I-II Exclusion criteria: history of opiate addiction, history of sensitivity to Tramadol, epilepsy or high ICP, chronic hepatic disease, chronic pain, obesity (BMI>30), taking of MAO inhibitors or SSRIs, any psychological or cognitional disorders that

prevent the post operative evaluations, the lack of patient tendency to continue the trial for any reason

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **96**

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
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences-Azadi square –Isfahan

City
Isfahan

Postal code

Approval date
2009-11-22, 1388/09/01

Ethics committee reference number
388328

Health conditions studied

1

Description of health condition studied
post-operative pain after open urologic surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
degree of pain

Timepoint
15, 30, and 60 minutes also 4, 8, 16, and 24 hours after surgery

Method of measurement
numeric rating scale

Secondary outcomes

1

Description
nausea and vomiting rate

Timepoint
15, 30, and 60 minutes also 4, 8, 16, and 24 hours after surgery

Method of measurement
nausea and vomiting score

2

Description
pulse rate

Timepoint
15, 30, and 60 minutes also 4, 8, 16, and 24 hours after surgery

Method of measurement
count of pulse at a minute

3

Description
sedation rate

Timepoint
15, 30, and 60 minutes also 4, 8, 16, and 24 hours after surgery

Method of measurement
sedation score

4

Description
respiratory rate

Timepoint
15, 30, and 60 minutes also 4, 8, 16, and 24 hours after surgery

Method of measurement
count of respiratory rate at a minute

5

Description
mean arterial pressure

Timepoint
15, 30, and 60 minutes also 4, 8, 16, and 24 hours after surgery

Method of measurement
(2 × systolic pressure + diastolic pressure) / 3

Intervention groups

1

Description
Tramadol, 1mg/kg in 10 cc normal saline 0/9%, with subcutaneous infiltration at the location of the incision, Before the incision
Category
Treatment - Drugs

2

Description
Tramadol, 2mg/kg in 10 cc normal saline 0/9%, with subcutaneous infiltration at the location of the incision, Before the incision
Category
Treatment - Drugs

3

Description
Tramadol, 10 cc normal saline 0/9%, with subcutaneous infiltration at the location of the incision, Before the incision
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali-Asghar hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences-Azadi square - Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
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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