Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparison of Opioid –Free Anesthesia with Conventional Balanced Anesthesia in Reducing Post-Operative Nausea and Vomiting in patients undergoing transurethral resection of bladder tumor or transurethral resection of prostate surgery: An RCT study.

Protocol summary

Summary

Patients undergoing anesthesia are at high risk of postoperative nausea and vomiting. Despite its prophylaxis, many patients suffer from postoperative nausea and vomiting and express this symptom as the worst or one of the worst experiences they had after the surgery. 1) Objectives: to study the effect of Opioid Free Anesthesia in reducing the incidence and severity of postoperative nausea and vomiting in comparison to conventional balanced anesthesia. 2) Design: prospective, randomized study 3) setting & conduct: Patients who are candidates for elective transurethral resection of bladder tumor and transurethral resection of prostate surgery, will be enrolled in this study. There will be two groups of patients. The first group will get Opioid-Free Anesthesia and the second one will receive conventional balanced anesthesia using opioids. Patients will be blind to their group assignment and consent forms will be obtained before the randomization. The hemodynamic changes will be perfectly managed by Trinitroglycerin and labetalol and the satisfactory pain management will be accomplished by non-opioid analgesics like paracetamol, ketorolac, ketamine and lidocaine. Nurses on the recovery unit and the ward and the investigator evaluating the patients and anesthesia outcome will be blinded to the group assignment. All patients will receive postoperative nausea and vomiting prophylaxis (ondansetron) if needed. The patients in both groups will also get paracetamol, ketorolac, ketamine and lidocaine for their pain management during the surgery. Paracetamol and ketorolac will be continued in the recovery unit and ward every 6 hours. Patients are also free to get morphine for breakthrough pain if needed in recovery unit or the surgery ward. The severity of postoperative nausea and vomiting will be assessed using a 4-points verbal rating scale (none, mild, moderate, and severe). The pain intensity will be recorded by an 11-points numeric rating scale. We will also evaluate, record and analyze the following data that will be obtained from the study: Height, weight, Body Mass Index, hemodynamic data, Bispectral index, and also trinitroglycerine, Labetalol, opioids consumption, arrhythmia, and quality of recovery. The statistician will be also blinded to the group assignment of patients. 4) Participants including major eligibility criteria: Candidates for transurethral resection of bladder tumor and transurethral resection of prostate surgery, Opioid naïf patients; Patients with American Society of Anesthesiologists class I – III. Exclusion criteria: Age <18 or >75 years old; Usage of High doses of opioids before the operation; Patients with allergy to any medication used in the study; Patients with hypertension or ischemic heart disease even if perfectly controlled; Patients who need to get any corticosteroids or any pro-kinetic medication; Patients with history of snoring or sleep apnea. 5) Interventions: In study group we will not use any opioid including fentanyl during the anesthesia; however, in control group we will provide the balanced anesthesia which contains opioids in the medications patients receive. 6) main outcome measures: The incidence and severity of postoperative nausea and vomiting will be assessed as the main outcome of this study. The outcome will be measured by using a 4-points verbal rating scale (none, mild, moderate, and severe).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102319640N1**
Registration date: **2015-12-26, 1394/10/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2015-12-26, 1394/10/05

Registrant information
Name
Hossein Majedi Ardakani
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2234 4084
Email address
hmajedi@tums.ac.ir

Recruitment status
Recruitment complete
Funding source
Urooncology research center of Tehran University of Medical Sciences

Expected recruitment start date
2016-01-21, 1394/11/01
Expected recruitment end date
2018-01-21, 1396/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison of Opioid –Free Anesthesia with Conventional Balanced Anesthesia in Reducing Post-Operative Nausea and Vomiting in patients undergoing transurethral resection of bladder tumor or transurethral resection of prostate surgery: An RCT study.

Public title
A Comparison of Opioid –Free Anesthesia with Conventional Balanced Anesthesia in Reducing Post-Operative Nausea and Vomiting in patients undergoing transurethral resection of bladder tumor or transurethral resection of prostate surgery: An RCT study.
Purpose
Treatment
Inclusion/Exclusion criteria
Exclusion criteria: Age <18 or >75; Usage of High doses of opioids before the operation; Patients with allergy to any medication used in the study; Patients with hypertension or ischemic heart disease even if perfectly controlled; Patients who have not completed their "Nothing Per Os" time; Patients who need to get any corticosteroids or any pro-kinetic medication; Patients with history of snoring or sleep apnea Inclusion criteria: Opioid naïf patients; Patients with American Society of Anesthesiologists class I – III.
Age
From **17 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **156**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committee of Tehran University of Medical scinces
Street address
Ghods Av., Keshavarz Boulevard,
City
Tehran
Postal code
Approval date
2015-08-10, 1394/05/19
Ethics committee reference number
IR.TUMS.REC.1394.554

Health conditions studied

1

Description of health condition studied
Hyperplasia of prostate
ICD-10 code
N40
ICD-10 code description
Hyperplasia of prostate

2

Description of health condition studied
Malignant neoplasm of bladder
ICD-10 code
C67
ICD-10 code description
Malignant neoplasm of bladder

Primary outcomes

1

Description
Post-Operative Nausea and Vomiting
Timepoint
The first day after the surgery
Method of measurement
Categorical rating scale

Secondary outcomes

1

Description
Pain intensity
Timepoint
The first day after the surgery
Method of measurement
Numeric rating scale

Intervention groups

1

Description
Intervention (study) Group: Opioid-free anesthesia: We will not use any opioid including fentanyl during the anesthesia in this group. The anesthesia will be administered by following drugs, including: Midazolam 2 mg IV, Thiopental 5 mg/kg IV, Atracurium 0.5 mg/kg IV, Lidocaine 100 mg IV, followed by 2 mg/kg/h, and Isoflurane 1.0 - 1.5%. Opioids will be substituted by paracetamol 1000 mg IV, ketorolak 30 mg IV and ketamine 0.5 mg/kg followed by 10 mg IV Q1H. Depth of anesthesia will be measured by BIS and will be kept in between 40-60.
Category
Treatment - Drugs

2

Description
Control Group: conventional (balanced) anesthesia: The anesthesia will be administered by following drugs, including: Midazolam 2 mg IV, Fentanyl 3 micg/kg, Thiopental 5 mg/kg IV, Atracurium 0.5 mg/kg IV, Lidocaine 100 mg IV, followed by 2 mg/kg/h, and Isoflurane 1.0 - 1.5%. Analgesia will be provided by paracetamol 1000 mg IV, ketorolak 30 mg IV and ketamine 0.5 mg/kg followed by 10 mg IV Q1H. Depth of anesthesia will be measured by BIS and will be kept in between 40-60.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hsopital
Full name of responsible person
Dr. Hossein Majedi
Street address
Department of Anesthesia and Pain Medicine, Imam Khomeini Hospital, Keshavarz Boulevard,Tehran
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 Mohammad Reza Nourozi
Street address
Imam Khomeini Hospital, Keshavarz Boulevard, Tehran
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
Imam Khomeini Hospital, Tehran university of medical sciences
Full name of responsible person
Dr. Hossein Majedi
Position
Anesthesiologist, Fellowship of Pain Management / Assistant Professor
Other areas of specialty/work
Street address
Department of Anesthesia and Pain Medicine, Imam

Khomeini Hospital, Keshavarz Boulevard,Tehran

City

Tehran

Postal code

Phone

+98 21 2234 4084

Fax

Email

hossein_majedi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Khomeini Hospital, Tehran University of medical sciences

Full name of responsible person

Dr. Hossein Majedi

Position

Anesthesiologist, Fellowship of Pain Management, Assistant Professor

Other areas of specialty/work

Street address

Department of Anesthesia and Pain Medicine, Imam Khomeini Hospital, Tehran University of medical sciences

City

Terhan

Postal code

Phone

+98 21 2234 4084

Fax

Email

hossein_majedi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Imam Khomeini Hospital, Tehran University of medical sciences

Full name of responsible person

Dr. Hossein Majedi

Position

Anesthesiologist, Fellowship of Pain Management

Other areas of specialty/work

Street address

Department of Anesthesia and Pain Medicine, Imam Khomeini Hospital, Tehran University of medical sciences

City

Tehran

Postal code

Phone

+98 21 2234 4084

Fax

Email

hossein_majedi@yahoo.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