

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of anesthesia depth monitoring by conventional and bispectral index on incidence and severity of nausea and vomiting after urologic surgeries

Protocol summary

Summary

The objective of this study is comparison of anesthesia depth monitoring by conventional and bispectral index on nausea and vomiting after urologic surgery. 180 participants who are candidate for abdominal urologic surgery at the single center with age range 20 to 60 years and The American Society of Anesthesiologists Physical Status classification I-II enroll in this phase3 clinical trial. Exclusion criteria is major comorbidity, prolonged operating time more than 2 hours and peritoneal manipulation. Patients and researchers who collect data blind of anesthesia depth monitoring kind. Patients before induction of anesthesia randomize to two groups with and without bispectral index monitoring. All steps before and during induction of anesthesia and the kind of using drugs is same in two groups. Drugs infusion set for bispectral index 40 -60 in the interventional group and in the control group, drugs infusion set to maintain heart rate and blood pressure in the range $\pm 20\%$ of baseline. During the first 24 hours after surgery, the incidence and severity of nausea and vomiting records for each patient. The same antiemetic drugs use if needed and prescription dose record every time. Incidence and severity of nausea and vomiting record every 30 minutes for 2 hours and every 6 hours to 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042312668N2**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

Reza Sari motlagh

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthesia depth monitoring by conventional and bispectral index on incidence and severity of nausea and vomiting after urologic surgeries

Public title

the effect of anesthesia depth on nausea and vomiting after surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Candidate for abdominal urologic surgery under general anesthesia; The American Society of Anesthesiologists (ASA) Physical Status classification I-II; Age range is 20 to 60 years. Exclusion criteria: Comorbidity such as liver disease, kidney disease, cardiovascular disease, central nervous system disease, gastrointestinal disease, pulmonary disease, metabolic disease and glaucoma; Blood transfusion need in operating time; Prolonged operating time (over than 2 hours); Past history of drugs hypersensitivity to using drugs; Drug history of emetic and anti-emetic drugs prior surgery; Pregnant or lactating women; Intraperitoneal surgery; Need to O2 therapy after surgery; Body mass index over than 30; motion sickness disease.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Patients and researchers who collect data is blinded from the anesthesia depth monitoring kind. The Two blocks with 90 fixed numbers is selected and two groups is randomized by Random Block of the sata" software

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Postal code**Approval date**

2015-10-12, 1394/07/20

Ethics committee reference number

TBZMED.REC.1394.607

Health conditions studied**1****Description of health condition studied**

Nausea and Vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and Vomiting

Primary outcomes**1****Description**

Incidence and severity of nausea and vomiting after surgery

Timepoint

every 30 minutes for 2 hours and every 6 hours to 24 hours after surgery.

Method of measurement

Questionnari and graded visual scale

Secondary outcomes**1****Description**

Decreased use of antiemetic drugs after surgery

Timepoint

Every 30 minutes for 2 hours and every 6 hours to 24 hours after surgery.

Method of measurement

Questionnaire

Intervention groups**1****Description**

Traditional anesthesia depth monitoring

Category

Prevention

2**Description**

Anesthesia depth monitoring by bispectral index

Category

Prevention

Recruitment centers**1****Recruitment center**

Name of recruitment center

Imam Reza Medical Research and Training Hospital
Full name of responsible person
Dr. Hamzeh Hoseinzadeh
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Imam Reza Medical Research and Training Hospital,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of
Medical Sciences
Full name of responsible person
Dr. Hasan Soleimanpour
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Faculty of Medicine, Tabriz University of Medical
Sciences, Golgasht street.
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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, Tabriz 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
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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