

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of monitoring of depth of anesthesia using bispectral index and clinical standard method in recovery of patients after gynecologic laparoscopic surgery

Protocol summary

Summary

Objectives: Monitoring the depth of anesthesia by using bispectral index and clinical standard method for recovery of patients after laparoscopic surgical in women. Design: Block randomization, triple blind, without placebo, single center, trial phase 2, including 80 patients undergoing laparoscopic surgery for women. Participants including major eligibility criteria: All patients undergoing laparoscopic surgery for women. Intervention: Intervention 1. Using standard method to measure the patient's consciousness during surgery Intervention 2. Using bispectral index to measure the patient's consciousness during surgery Main outcome measures: Time of discharge from recovery, Amount of used narcotics, Pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122919715N2**

Registration date: **2016-01-12, 1394/10/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-12, 1394/10/22

Registrant information

Name

Arash Pourbakhshandeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

alimyan.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of monitoring of depth of anesthesia using bispectral index and clinical standard method in recovery of patients after gynecologic laparoscopic surgery

Public title

Evaluation of depth of anesthesia using two different methods in gynecologic laparoscopic surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; ASA class I-III; patients undergoing laparoscopic surgery for women; no history of chronic obstructive pulmonary disease; lack of kidney dysfunction; lack of neurologic disease; lack of addiction to opium or alcohol; not taking anticonvulsants and antidepressants; Lack of hypertension; lack of heart failure; patients with emergent surgery. Exclusion criteria: Patients with difficult airway; Drug allergy.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-12-02, 1394/09/11

Ethics committee reference number

lr.iums.rec.13949111174020

Health conditions studied

1

Description of health condition studied

gynecologic surgery

ICD-10 code

O75.4

ICD-10 code description

Other complications of obstetric surgery and procedures

Primary outcomes

1

Description

Time of discharge from recovery

Timepoint

After the end of surgery

Method of measurement

Aldrete score

2

Description

Amount of used narcotics

Timepoint

Within the surgery

Method of measurement

Quantitative

3

Description

Pain

Timepoint

Within the surgery

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1. Using standard method including blood pressure and pulse rate to measure the patient's consciousness during surgery

Category

Prevention

2

Description

Intervention 2. Using bispectral index to measure the patient's consciousness during surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-e Akram hospital

Full name of responsible person

Dr Azadeh Azizi

Street address

Rasool-e Akram hospital, Niyayesh street, Satarkhan street, Tehran, Iran

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, Vice Chancellor
for Research

Full name of responsible person

Dr Seyed Mohsen Ziaiefard

Street address

Headquarters building, 5th floor, intersection of
Sheikh Fazl-Allah Noori and Shahid Chamran, Western
Hemmat highway, Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences, Vice Chancellor for
Research

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

Iran University of Medical Sciences

Full name of responsible person

Dr Azadeh Azizi

Position

Anesthesiology resident

Other areas of specialty/work

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Person responsible for updating data

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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