

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of depth of anesthesia in patients under general anesthesia with Propofol or Isofluran undergoing total abdominal hysterectomy with bispectral index

Protocol summary

Summary

Measurement of depth of anesthesia during surgery in different types of anesthesia (volatile and intravenous) in patients who monitored based on hemodynamic changes, is the aim of this study. In this randomised single blind trial, 24 women 35-65 years old with no history of cardiac disease, hypertension, diabetes, renal or hepatic disease, no history of allergy to egg candidate for total abdominal hysterectomy will be chosen. After similar induction of anesthesia, anesthesia will be maintained with volatile anesthetic (Isoflurane) or intravenously (propofol) and resident or technician of anesthesia will be permitted to increase or decrease dose of anesthetics based on blood pressure changes on a determined protocol. Depth of anesthesia, will be measured at the beginning of anesthesia, after induction and intubation and in minutes 30 and 60 and blood pressure and heart rate will be recorded too. Mean of measurements will be compared between two groups and difference in depth of anesthesia and awareness between two groups will be recorded.

General information

Acronym

changes in depth of anesthesia during anesthesia with propofol and isoflurane

IRCT registration information

IRCT registration number: **IRCT201112024969N5**

Registration date: **2012-01-15, 1390/10/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-15, 1390/10/25

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

drpournajafian@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of depth of anesthesia in patients under general anesthesia with Propofol or Isoflurane undergoing total abdominal hysterectomy with bispectral index

Public title

Comparison of depth of anesthesia in patients under general anesthesia with Propofol or Isoflurane undergoing total abdominal hysterectomy with bispectral index

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women ASA I, II candidate for total abdominal hysterectomy. Exclusion criteria: Ages less than 35 and more than 65 years old; history of cardiac disease; hypertension; diabetes; renal or hepatic disease; no history of allergy to egg or propofol in previous anesthesia (if she had); heart rate and blood pressure changes more than 30% of baseline; any vasoactive or vasodilator injection requirement more than expected in protocol.

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Ghods st. - keshavarz blvd.

City

Tehran

Postal code

Approval date

2011-11-27, 1390/09/06

Ethics committee reference number

1811/130/90/ص

Health conditions studied

1

Description of health condition studied

depth of anesthesia and blood pressure

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

depth of anesthesia

Timepoint

at the beginning of anesthesia, then every 30 minutes

Method of measurement

number from 100, by BIS

2

Description

systolic blood pressure

Timepoint

at the beginning of anesthesia, then every 30 minutes

Method of measurement

automatic

3

Description

diastolic blood pressure

Timepoint

at the beginning of anesthesia, then every 30 minutes

Method of measurement

automatic

4

Description

heart rate

Timepoint

at the beginning of anesthesia, then every 30 minutes

Method of measurement

puls oxymeter

Secondary outcomes

empty

Intervention groups

1

Description

Anesthesia with Isoflurane as 0.6 to 1.4 % of inspiratory gas

Category

Treatment - Other

2

Description

Anesthesia with intravenous Propofol infusion 100 to 200 microgram per kilogram body weight

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Alireza Pournajafian

Street address

Beh Afarin st. Karim Khan blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Mrs. Alamdar

Street address

Ghods st. - keshavarz blvd.

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 Science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Alireza Pournajafian

Position

Assistant professor of anesthesia

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Assistant professor of anesthesia

Other areas of specialty/work

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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