Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (Isoflorane) or interavenously (propofol) and resident or technician of anesthesia will be permitted to 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 wil 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 Sciense

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 Isofluran 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 Isoflorane 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
Street address
Firoozgar Hospital, Beh Afarin st., karim khan Ave.
City
Tehran
Postal code
1593748711
Phone
+98 21 8894 6762
Fax
Email
a-pournajafian@tums.ac.ir alipn78@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Firoozgar Hospital, Beh Afarin st., karim khan blvd.
City
Tehran
Postal code
1593748711
Phone
+98 21 8894 6762
Fax
+98 21 8894 2622
Email
a-pournajafian@tums.ac.ir alipn78@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