

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparative cost-effectiveness analysis of intravenous propofol anesthesia and inhalational isoflurane anesthesia in patients undergo open surgery with bispectral monitoring at Shahroud's Imam Hossein hospital

Protocol summary

Summary

In the recent years, physicians and health care centers focused on effectiveness and cost of medical procedures. This single blind clinical trial is designed to compare and evaluate the costs and benefits of two anesthetic methods, fentanyl/ propofol anesthesia versus fentanyl/isoflurane anesthesia. Among surgical patients in Shahroud's Imam Hossein hospital, 100 consecutive adult man or woman with 18 to 60 years old will be selected and informed about the study. Inclusion criteria are: an anesthesia risk of 1 or 2 (According to American society of anesthesiologist's classification); orthopedic or reconstructive operations on extremities; hip and pelvic operations; Inguinal hernioraphy; abdominal hernioraphy; cholecystectomy; appendectomy. Patients with a history of opiates or alcohol abuse, sedative and anticonvulsive therapy, anesthesia or surgical complications will be excluded from the study. Measurable outcomes during procedures are BIS index, systolic blood pressure, pulse rate, sweating, pupil's size and light reflex. Postoperative pain, agitation, nausea and vomiting and also, Modified Alderet scoring system (MASS) will be assessed in post anesthesia care unit. Finally, we will calculate anesthesia cost in each participant. Measurable outcomes during procedures are BIS index, systolic blood pressure, pulse rate, sweating, pupil's size and light reflex. Postoperative pain, agitation, nausea and vomiting and also, Modified Alderet scoring system (MASS) will be assessed in post anesthesia care unit. Finally, we will calculate anesthesia cost in each participant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022712123N2**

Registration date: **2013-09-07, 1392/06/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-07, 1392/06/16

Registrant information

Name

Javad Nourian

Name of organization / entity

Imam Hossein Hospital, Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 27 3334 2001

Email address

javadnourian@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research, Shahroud University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative cost-effectiveness analysis of intravenous propofol anesthesia and inhalational isoflurane anesthesia in patients undergo open surgery with bispectral monitoring at Shahroud's Imam Hossein hospital

Public title

Cost-effectiveness analysis of intravenous propofol anesthesia versus inhalational Isoflurane anesthesia in patients undergo open surgery at Shahroud's Imam Hossein hospital.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Man or woman with 18 to 50 years old; an anesthesia risk of 1 or 2 (According to American society of anesthesiologist's classification); orthopedic or reconstructive operations on extremities; hip and pelvic operations; Inguinal hernioraphy; abdominal hernioraphy; cholecystectomy; appendectomy. Exclusion criteria: Patients with a history of opiates or alcohol abuse; sedative and anticonvulsive therapy; anesthesia or surgical complications during operation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics committee, Deputy of research, Shahroud University of Medical Sciences

Street address

Ethics committee, Deputy of research, Shahroud University of Medical Sciences, 7th of Tir square, Shahroud, Iran. Postal code: 3614773955

City

Shahroud

Postal code

3614773955

Approval date

2013-01-09, 1391/10/20

Ethics committee reference number

9112

Health conditions studied

1

Description of health condition studied

Calculus of gallbladder with acute cholecystitis

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

2

Description of health condition studied

Anesthesia for appendectomy

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

3

Description of health condition studied

Ventral hernia without obstruction or gangrene

ICD-10 code

K43.9

ICD-10 code description

Ventral hernia

4

Description of health condition studied

Unilateral or unspecified inguinal hernia, without obstruction or gangrene

ICD-10 code

K40.9

ICD-10 code description

Unilateral or unspecified inguinal hernia, without obstruction or gangrene

5

Description of health condition studied

Abnormal uterine and vaginal bleeding, unspecified

ICD-10 code

N93.9

ICD-10 code description

Abnormal uterine and vaginal bleeding, unspecified

6

Description of health condition studied

Fracture of neck of femur

ICD-10 code

S72

ICD-10 code description

Fracture of femur

7

Description of health condition studied

Fracture of lower leg, including ankle

ICD-10 code

S82

ICD-10 code description

Fracture of lower leg, including ankle

8

Description of health condition studied

Fracture of upper limb, level unspecified

ICD-10 code

T10

ICD-10 code description

Fracture of upper limb, level unspecified

Primary outcomes

1

Description

BIS (Depth of anesthesia)

Timepoint

Every 5 minutes during operation

Method of measurement

By using Danmeter's Cerebral State Monitor (Model CSM2) and record BIS index as an exact number from 0 to 100 every 5 minutes

2

Description

Heart rate

Timepoint

before procedure and every 5 minutes during operation

Method of measurement

Novin saadat's cardiac monitoring and record as beat per minute

3

Description

Systolic blood pressure

Timepoint

before procedure and every 5 minutes during operation

Method of measurement

Novin saadat's automatic Non invasive BP monitoring and record as mmHg

4

Description

Pupil's reflex

Timepoint

Every 5 minutes during operation

Method of measurement

Clinical observation and chart as Yes or No

5

Description

Pupil's size

Timepoint

every 5 minutes during procedure

Method of measurement

Clinical observation and chart as an exact number from 1 to 10 (millimeter)

6

Description

Sweating

Timepoint

Every 5 minutes during operation

Method of measurement

Clinical observation and chart as Yes or No

Secondary outcomes

1

Description

Postoperative agitation

Timepoint

Every 5 minutes during recovery

Method of measurement

Clinical observation and chart as Yes or No

2

Description

Postoperative nausea and vomiting

Timepoint

Every 5 minutes during recovery

Method of measurement

Clinical observation and chart as Yes or No

3

Description

Recovery time

Timepoint

Every 5 minutes during recovery

Method of measurement

The end of recovery will be determined by Modified Alderet scoring system (MASS). In this system, scoring 9 points in 5 variables of consciousness, circulation (systemic blood pressure), breathing, SPO2, and activity, each of 2 points, specifies the end of recovery

4

Description

Postoperative pain

Timepoint

Every 5 minutes during recovery

Method of measurement

Clinical observation and chart as Yes or No

5

Description

Anesthesia cost

Timepoint

Time of discharge

Method of measurement

Total drug's (Isoflurane or Propofol) cost in Rial

Intervention groups

1

Description

In control group, premedication will be Fentanyl (1 µg/kg) and midazolam 0.05 mg/kg. Induction of anesthesia is intravenous propofol with dose of 1.5 mg/kg Maintenance of anesthesia will be performed with a concentration of 2% isoflurane (1.7 MAC) in combination with equal amount of N2O / O2 , Every 5 minutes isoflurane concentration will be adjusted according to depth of anesthesia.

Category

Treatment - Drugs

2

Description

In intervention group premedication is Fentanyl (1 µg/kg) and midazolam 0.05 mg/kg. Induction of anesthesia is intravenous propofol with dose of 1.5 mg/kg Maintenance of anesthesia intravenous propofol will be started at a rate of 140 µg/kg/hours in combination with equal amount of N2O / O2 , Every 5 minutes propofol infusion rate will be adjusted according to depth of anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Operation room, Imam Hossein hospital

Full name of responsible person

Javad Nourian MD

Street address

End of Ayatollah Towhidi avenue, Imam Hossein hospital, Shahroud, Iran

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research, Shahroud University of Medical Sciences

Full name of responsible person

Ahmad Khosravi

Street address

Deputy of research, Shahroud University of Medical Sciences, 7th of Tir square

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of research, Shahroud 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 Hossein Hospital, Shahroud University of Medical Sciences, Shahroud, Iran

Full name of responsible person

Javad Nourian MD

Position

Assistant professor of anesthesiology, department of anesthesia and intensive care

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Javad Nourian MD

Position

Assistant professor of anesthesiology, department of anesthesia and intensive care

Other areas of specialty/work

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Person responsible for updating data

Contact

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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