Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The effect of the Bispectral Index (BIS) during induction of anesthesia on the amount of propofol in patients undergoing various surgical procedures.

Protocol summary

Study aim
Evaluating the effect of Bispectral Index (BIS) during anesthesia induction on the amount of propofol consumption in patients undergoing various surgical procedures

Design
In this randomized clinical trial study, patients will be selected by simple random sampling and will be divided into two groups by block randomization. According to the sample size of 80 (40 cases and 40 controls) there will be in 8 blocks of 10 individuals.

Settings and conduct
This study will be conducted in Zahedan University of Medical Sciences hospitals. Control group will be given general anesthesia based on clinical symptoms and treatment group based on Bispectral Index (BIS). First, both groups get the same amount of anesthetic drug. The control group will receive propofol 0.2mg every 20 seconds until there is no response to stimulation and complete anesthesia; the experimental group will receive 0.5 mg every 20 seconds until the BIS is reduced to less than 60. The amount of propofol during anesthesia induction, heart rate and mean arterial blood pressure will be recorded before and after intubation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- ASA Class I & II 2- Age between 18 and 65 Exclusion criteria: 1-History of problem in intubation 2-Loss of consciousness before surgery 3-Brain surgery 4-Cardiovascular disease 5-Esophageal reflex 6-Hiatus hernia 7-liver or renal failure 8-sensitivity to the drugs 9-Sedative or substance administration within 24 hours before surgery 10-History of any neurological disorders and use of psychiatric drugs 11-Patient history of addiction 12- hemoglobin < 10 mg/dL 13-Patient dissatisfaction with study participation

Intervention groups
Experimental group (using BIS) Control Group (non BIS)

Main outcome variables
Amount of propofol Mean arterial pressure Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190813044521N1**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **prospective**

Last update: **2019-11-23, 1398/09/02**
Update count: **0**

Registration date
2019-11-23, 1398/09/02

Registrant information

Name
MARYAM HOJJAT

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3221 0940

Email address
maryyhojjat@gmail.com

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2640-12-22, 2019/10/01

Expected recruitment end date
2641-10-23, 2020/08/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the Bispectral Index (BIS) during induction of anesthesia on the amount of propofol in patients undergoing various surgical procedures.

Public title

The effect of the Bispectral Index (BIS) on the drug dosage during induction of anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- ASA Class I & II population between the ages of 18 and 65

Exclusion criteria:

-History of intubation problem before or in doubt Loss of consciousness before surgery without reason Brain surgery Cardiovascular disease Esophageal reflax6- Hiatus hernia liver or renal failure sensitivity to the drugs Sedative or substance administration within 24 hours before surgery History of any neurological disorders and use of psychiatric drugs Patient history of addiction1 hemoglobin < 10 mg/dL Patient dissatisfaction with study participation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization Block randomization with two group treatment (A and B), and block size equal 8 with 80 sample size (40 sample in each group) based random allocation generated by soft wear will be use. Base this method, create 10 blocks to assign sample numbers equally to each group.

Blinding (investigator's opinion)

Not 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 of Zahedan University of Medical Sciences

Street address

9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.ZAUMS.REC.1398.199

Health conditions studied

1

Description of health condition studied

Elective general anesthesia

ICD-10 code

Y70.0

ICD-10 code description

Diagnostic and monitoring anesthesiology devices associated with adverse incidents

Primary outcomes

1

Description

amount of propofol

Timepoint

20 seconds

Method of measurement

Syringe

2

Description

Mean arterial pressure

Timepoint

before induction (baseline), immediate after induction, immediate after intubation, and 5 min after intubation

Method of measurement

Sphygmomanometer

3

Description

heart beat

Timepoint

before induction (baseline), immediate after induction,

immediate after intubation, and 5 min after intubation

Method of measurement

heart rate monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of a bispectral index (BIS)

Category

Treatment - Devices

2

Description

Control group: Without Use of a bispectral index (BIS)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences Hospitals

Full name of responsible person

Sharam Bojian Borujeni

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nour Mohamad Bakhshani

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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

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Hojjat

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable