

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Use of Isoflurane with depth anesthesia monitoring (Bispectral Index) and its effect on the recovery of elderly patients

Protocol summary

Summary

We have studied the influence of using BIS index (Bispectral index) in recovery of elderly patients undergoing abdominal surgery anaesthetized with isoflurane. This study was designed to investigate whether BIS monitoring improves clinical anesthetic delivery, recovery profiles in elderly patients undergoing abdominal surgery with general anesthesia compared to standard clinical practice (without monitoring) . The study group included 68 patients having American Society of Anesthesiologists (ASA) physical status of I to III who were scheduled for elective abdominal surgery. Patients were randomly allocated into two groups that receiving general anesthesia with BIS monitoring and without using of BIS. Inclusion criteria were abdominal surgery, ASA (American Society of Anesthesiologists) physical status of I to III, over the age of 60 and exclusion criteria were a history of psychotic disorders, dementia, previous CVA (cerebrovascular accident), head trauma, and drug abuse . In both groups standard monitoring was used, including BIS recording via two bipolar electroencephalographic leads. The main outcome is recovery time and discharge from recovery.

General information

Acronym

BIS monitoring

IRCT registration information

IRCT registration number: **IRCT201101121481N1**

Registration date: **2011-05-10, 1390/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-10, 1390/02/20

Registrant information

Name

Amir Asadi

Name of organization / entity

Hamedan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 81 1828 1440

Email address

asadi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences and Health Services

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Use of Isoflurane with depth anesthesia monitoring (Bispectral Index) and its effect on the recovery of elderly patients

Public title

Use of Isoflurane with depth anesthesia monitoring (Bispectral Index) and its effect on the recovery of elderly patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: elderly patients with grade ASA (American Society of Anesthesiologists) I to III, have over 60 years of age for the intra-abdominal surgery (Cholecystectomy, ...). Exclusion Criteria: Psychotic disorders, Dementia, Previous CVA, Head trauma, and Drug abuse.

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

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

Hamedan University of Medical Sciences and Health Services

Street address

Hamedan University of Medical Sciences and Health Services

City

Hamedan

Postal code

8736-3-65178

Approval date

2008-07-26, 1387/05/05

Ethics committee reference number

56581/9/35/16/پ

Health conditions studied

1

Description of health condition studied

general anesthesia

ICD-10 code

Y84

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

Measuring Depth of Anesthesia

Timepoint

Continuously during surgery

Method of measurement

By bipolar electroencephalographic leads that connected to the temporal and frontal area of patients and brain waves evaluated by BIS monitoring according to numbers from 0 to 100.

Secondary outcomes

1

Description

awakening and discharge from recovery

Timepoint

awakening time and discharge from recovery

Method of measurement

According to Alderet Score

Intervention groups

1

Description

A: Standard practice (control group): receive general anesthesia and administration of anesthesia drugs was performed according to patients clinical evaluation in during surgery.

Category

Other

2

Description

B: BIS Group (test group): receive general anesthesia and administration of anesthesia drugs was performed according to BIS monitoring guided titration in during surgery.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Amir Asadi

Street address

Besat Hospital
City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Hamedan University of
Medical Sciences and Health Services

Full name of responsible person

Dr. Ali Ghaleiha

Street address

Vice chancellory for Research, Hamedan University of
Medical Sciences and Health Services

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research , Hamedan University of
Medical Sciences and Health Services

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

Vice chancellor for research , Hamedan University of
Medical Sciences and Health Services

Full name of responsible person

Dr. Ali Ghaleiha

Position

Associate Professor

Other areas of specialty/work

Street address

Hamedan University of Medical Sciences and Health
Services

City

Hamedan

Postal code

Phone

+98 81 1827 6296

Fax

Email

ghaleiha@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences and Health
Services

Full name of responsible person

Amir Asadi

Position

M.sc

Other areas of specialty/work

Street address

Hamedan University of Medical Sciences and Health
Services

City

Hamedan

Postal code

Phone

+98 81 1828 1440

Fax

Email

asdadi@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences and Health
Services

Full name of responsible person

Amir Asadi

Position

M.sc

Other areas of specialty/work

Street address

Hamedan University of Medical Sciences and Health
Services

City

Hamedan

Postal code

65178-3-8736

Phone

+98 81 1828 1440

Fax

+98 81 1828 1442

Email

asadi@umsha.ac.ir

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