Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of low thoracic epidural anesthesia combined with total intravenous anesthesia on dose requirement for induction and monitoring of depth of anesthesia guided by bispectoral index in patients under upper abdomen surgeries: randomized clinical trial

Protocol summary

Summary

The purpose of this randomized trial is to evaluate the effect of thoracic epidural anesthesia combined with total intravenous anesthesia on dose requirement for induction &BIS in upper abdominal surgeries. A total of 40 patients with ASA (American Society of Anesthegiologist)1&2class, will be randomly located in two groups (intervention & control). After insertion of epidural catheter, patients receive bupivacaine 0.25% 0.7ml/m/seg for 10 segments. After complete of block, induction will be started with 1mg/s protocol infusion. When BIS (BIS PECTORAL INDEX) <50, patient will receive cisatra 0.15ml/kg & will be intubated .Then maintenance will be by propofol & remifentanyl infusion. In control group, patients will receive normal saline with the same volume in epidural space. At the end of surgery, drugs infusion will be discontinued. After estuation & reverse, patient will be transferred to recovery. Up to 30 minutes of surgery, heart rate, blood pressure, BIS, propofol dose will be recorded and compared between two groups. TIVA (total intra venous anesthesia); BIS (Bispectral index); MAC (minimal alveolar concentration)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111074731N9**
Registration date: **2012-03-03, 1390/12/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-03, 1390/12/13

Registrant information

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Recruitment status

Recruitment complete

Funding source
Research vice-chancellor of Tabriz University of Medical Sciences

Expected recruitment start date
2011-08-23, 1390/06/01

Expected recruitment end date
2012-06-21, 1391/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of low thoracic epidural anesthesia combined with total intravenous anesthesia on dose requirement for induction and monitoring of depth of anesthesia guided by bispectoral index in patients under upper abdomen surgeries: randomized clinical trial

Public title

The effect of thoracic epidural combined with total intravenous anesthesia on dose requirement for induction of anesthesia & bis pectoral index

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Adult patients, belonging to ASA 1&2 class; undergoing elective upper abdomen surgeries. Exclusion criteria: vertebral abnormality; neurologic disorders; cardio vascular diseases; Hgb <12; renal or hepatic failure; chest trauma; Allergy to local anesthetics; Plt <100000; Coagulopathy, βblockers.

Age

From **18 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research vice-chancellor of Tabriz university of medical sciences

Street address

Tabriz university of medical sciences, Golgasht

City

Tabriz

Postal code

Approval date

2011-06-28, 1390/04/07

Ethics committee reference number

5/4/2756

Health conditions studied

1

Description of health condition studied

BIS changes due to thoracic epidural anesthesia

ICD-10 code

T66 -T78

ICD-10 code description

Other and unspecified effects of external causes

2

Description of health condition studied

anesthesia drug dose changes due to thoracic epidural

ICD-10 code

T66 - T78

ICD-10 code description

Other and unspecified effects of external causes

Primary outcomes

1

Description

Oxygen Saturation

Timepoint

before epidural, after epidural, before pre med, 3min after pre med, pre induction, post induction, after intubation, each 5min after surgery

Method of measurement

pulse oxymetry devices

2

Description

Mean arterial blood pressure

Timepoint

before epidural, after epidural, before pre med, 3min after pre med, pre induction, post induction, after intubation, each 5min after surgery

Method of measurement

with automatic cuff

3

Description

BIS

Timepoint

before epidural, after epidural, before pre med, 3min after pre med, pre induction, post induction, after intubation, each 5min after surgery

Method of measurement

BIS devices

4

Description

Propofol dose for induction & maintenance of anesthesia

Timepoint

Afer intubation, after extubation

Method of measurement

Infusion pump

5

Description

heart rate

Timepoint
before epidural, after epidural, before pre med, 3min after pre med, pre induction, post induction, after intubation, each 5min after surgery
Method of measurement
continuous ECG monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after epidural catheter insertion marcaine 0.25%,0.7ml/m/seg for 10 segments will be adminstered
Category
Other

2

Description
Control group: after epidural catheter insertion ,normal saline with same volume of marcaine will be adminstered
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Hosseinzade Hamze
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research vice-chancellor of Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Reza Rashidi
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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
Research vice-chancellor of Tabriz 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

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Person responsible for updating data

Contact

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