Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

Evaluation of postoperative cognitive disorders in non-emergent spinal surgery patients undergoing intravenous and isoflurane anesthesia

Protocol summary

Study aim
Determination of cognitive disorders after surgery between anesthesia with isoflurane and anesthesia with complete intravenous drugs in patients undergoing spinal surgery

Design
Clinical trial, parallel group, 65 patients will be randomly selected

Settings and conduct
This trial will be conducted on patients who undergo elective spinal surgery, Shariati Hospital,Tehran,Iran.Patients are intervened in the spine surgery room of Shariati Hospital. Patients as well as the person who examines and records postoperative cognitive disorders are unaware of the type of intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients aged 18-65 years(ASA I-III)who undergo non-emergency spinal surgery at Shariati Hospital Exclusion criteria: use of psychiatric drugs, mental retardation, history of dementia, history Brain surgery, and dissatisfaction with participation in the study and the patient's death after surgery.

Intervention groups
The intervention group includes patients undergoing elective spinal surgery who receive complete intravenous anesthesia. The comparison group includes patients undergoing elective spinal surgery who receive isoflurane anesthesia.

Main outcome variables
Cognitive disorders

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211023052849N3**
Registration date: **2022-06-08, 1401/03/18**
Registration timing: **retrospective**

Last update: **2022-06-08, 1401/03/18**
Update count: **0**

Registration date
2022-06-08, 1401/03/18

Registrant information
Name
Arash Heroabadi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-24, 1400/12/05

Expected recruitment end date
2022-06-05, 1401/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of postoperative cognitive disorders in non-emergent spinal surgery patients undergoing intravenous and isoflurane anesthesia

Public title
The effect of anesthesia types on cognitive disorders after spinal surgery

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
≥ 18 years of age and maximum 65 Class 1 to 3 ASA anesthesia Absence of heart failure (EF <20%) No uncontrolled blood pressure or diabetes No pregnancy Willingness and satisfaction to participate in the project
Exclusion criteria:
Emergent surgery Patient dissatisfaction with continued participation in the study Pregnant women History of using psychiatric medications History of dementia History of brain surgery History of schizophrenia Recent alcohol or opioid use Severe anxiety Mental retardation Recent stroke
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator

Sample size
Target sample size: **65**
Randomization (investigator's opinion)
Randomized
Randomization description
This research uses individual randomization method. The random number sequence is generated using the "Randomization.com" website with a simple randomization method. The rest of the patients are in the group of total intravenous anesthesia (TIVA). Anesthesia is performed by an anesthesiologist and a second anesthesiologist who is not aware of the patients' randomization examines the patients for cognitive impairment.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patient's physician, who is the lead researcher, induces anesthesia, and the second anesthesiologist, who has no knowledge of patient's randomization, examines patients for cognitive impairment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Keshavarz Blvd, Qarib street
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2020-09-29, 1399/07/08
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.563

Health conditions studied

1

Description of health condition studied
Spine surgery
ICD-10 code
S24.2XXD
ICD-10 code description
Injury of nerve root of thoracic spine, subsequent encounter

Primary outcomes

1

Description
Cognitive disorders
Timepoint
Before induction of anesthesia, 6 ,12 , and 24 hours after Recovery
Method of measurement
Mini Mental State Examination questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Group 1 will be patients who are candidates for elective spinal surgery and will receive anesthesia with complete intravenous drugs by propofol induction dose(2-2.5 mg/kg IV) .After induction of anesthesia, patients received propofol as a continuous injection (using an infusion pump) at a dose of 50 to 100 µg / kg / min to maintain anesthesia. Proposol brand was BBRAUN (Germany).
Category
Treatment - Drugs

2

Description

Group 2 will be patients who are candidates for elective spinal surgery and will receive 1.5 - 3 % isoflurane anesthesia.After induction of anesthesia, isoflurane inhaled anesthetic gas with MAC 1.2 to 2% (by Drager anesthesia machine) was used to maintain anesthesia.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital

Full name of responsible person
Arsh Heroabadi

Street address
Tehran, North Kargar St., Jalal Al-Ahmad Intersection, Shariati Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Arash Heroabadi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared.
When the data will become available and for how long
Access starting after publication
To whom data/document is available
Clinical researchers and physicians
Under which criteria data/document could be used
Decision upon request
From where data/document is obtainable
Via email of Dr Arash Heroabadi
aheroabadi@sina.tums.ac.ir
What processes are involved for a request to access data/document
Formal inquiry.
Comments