

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

Registration timing: **retrospective**

Study aim

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

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

Update count: **0**

Registration date

2022-06-08, 1401/03/18

Design

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

Registrant information

Name

Arash Heroabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

Recruitment status

Recruitment complete

Funding source

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 of brain surgery, and dissatisfaction with participation in the study and the patient's death after surgery.

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

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.

Scientific title

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

Main outcome variables

Cognitive disorders

Public title

The effect of anesthesia types on cognitive disorders after spinal surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211023052849N3**

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

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. Propofol 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

Street address

Poursina alley, Keshavarz Blvd, 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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Person responsible for scientific inquiries

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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