

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Sep 2026

Effect of spinal anesthesia on the amount of postoperative cognitive dysfunction: A clinical trial

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Effect of spinal anesthesia on the amount of postoperative cognitive dysfunction

Design

This clinical trial with before and after anesthesia design was conducted on 100 patients who were surgery candidates under spinal anesthesia selected.

Settings and conduct

This study included 100 patients with ASA I or II who were candidate for surgery under spinal anesthesia at Besat Hospital, Hamadan, Iran. Patients will receive bupivacaine with fentanyl for spinal anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 60 years of age or higher; ASA I or II candidates for surgery under spinal anesthesia. Exclusion criteria: History of alcohol and sedative as well as anticonvulsant drug consumption, and drug abuse; Spinal anesthesia contraindications (local infection on the spinal needle region, sepsis, bleeding disorders, low platelet count, utilization of anticoagulants, brain lesions, anatomical disorders on spinal cord, and loss of blood volume)

Intervention groups

The intervention group will receive 10-12 mg of bupivacaine 0.5% with 50 µg fentanyl for spinal anesthesia.

Main outcome variables

The amount and severity of postoperative cognitive dysfunction will be evaluated and compared before, immediately after, and 10 months after spinal anesthesia.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190429043414N1**

Registration date: **2019-05-25, 1398/03/04**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Hossein Kimiaei Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3525 0182

Email address

kimiaeimd@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of spinal anesthesia on the amount of postoperative cognitive dysfunction: A clinical trial

Public title

Effect of spinal anesthesia on postoperative cognitive dysfunction

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
60 years of age or higher ASA I candidates for surgery under spinal anesthesia ASA II candidates for surgery under spinal anesthesia

Exclusion criteria:
History of alcohol and sedative as well as anticonvulsant drug consumption, and drug abuse Spinal anesthesia contraindications (local infection on the spinal needle region, sepsis, bleeding disorders, low platelet count, utilization of anticoagulants, brain lesions, anatomical disorders on spinal cord, and loss of blood volume)

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Ayatollah Kashani Boulevard, Khaje Rashid Cross Roads

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.UMSHA.REC.1398.003

Health conditions studied

1

Description of health condition studied

Postoperative cognitive dysfunction

ICD-10 code

F19

ICD-10 code description

Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

Primary outcomes

1

Description

The amount and severity of postoperative cognitive dysfunction

Timepoint

Before, immediately after, and 10 months after spinal anesthesia.

Method of measurement

Wechsler Memory Scale-III (WMS-III) and the Mini Mental State Examination (MMSE)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 10-12 mg of bupivacaine 0.5% with 50 µg fentanyl for spinal anesthesia.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Hossein Kimiaei Assadi

Street address

Besat Hospital, Shahid Motahari Boulevard, Resalat Square

City

Hamadan

Province

Hamadan

Postal code

6514845471

Phone

+98 81 3265 0030

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Ayatollah
Kashani Boulevard, Khaje Rashid Cross Roads

City

Hamadan

Province

Hamadan

Postal code

64517669644

Phone

+98 81 3820 1506

Email

info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Hossein Kimiaei Assadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hamadan University of Medical Sciences, Ayatollah
Kashani Boulevard, Khaje Rashid Cross Roads.

City

Hamadan

Province

Hamadan

Postal code

6517838678

Phone

+98 81 3525 0182

Email

hkimiaeimd@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Hossein Kimiaei Assadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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hkimiaeimd@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Hossein Kimiaei Assadi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total data to be included are the primary and

secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Hossein Kimiaei Assadiprotides the analysis code to the applicants via email: hkimiaeimd@yahoo.com

What processes are involved for a request to access data/document

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments