

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the frequency of delirium after abdominal surgery in patients receiving general anesthesia and spinal anesthesia.

Protocol summary

Study aim

Comparison of the frequency of delirium after abdominal surgery in patients receiving general anesthesia and spinal anesthesia

Design

A two-group, parallel-group, non-blinded, non-randomized, phase 3 clinical trial on 66 patients

Settings and conduct

This study will be conducted in Bu Ali Hospital, Tehran in 2025. We will divide patients into two groups: A (general anesthesia) and B (spinal anesthesia). After entering the operating room, patients will be placed under general anesthesia or spinal anesthesia. After surgery and during the postoperative hospitalization, patients will be monitored for delirium. Demographic data will also be extracted from the patients' records.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age 15-65 years Signed personal consent form to enter the study Elective surgery
Exclusion criteria Operation duration more than 4 hours Unusual bleeding during surgery

Intervention groups

Patients are placed in two groups: A (general anesthesia) and B (spinal anesthesia).

Main outcome variables

Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250113064376N1**
Registration date: **2025-02-18, 1403/11/30**
Registration timing: **prospective**

Last update: **2025-02-18, 1403/11/30**

Update count: **0**

Registration date

2025-02-18, 1403/11/30

Registrant information

Name

Arezoo Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7670 2535

Email address

wiish1999@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-20, 1403/12/30

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the frequency of delirium after abdominal surgery in patients receiving general anesthesia and spinal anesthesia.

Public title

Comparison of the frequency of delirium after abdominal surgery in patients receiving general anesthesia and spinal anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 15-65 years Signing the personal consent form to enter the study Electiveness of the surgery

Exclusion criteria:

Unusual bleeding during surgery Operation duration more than 4 hours

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address

Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St, Ayane Blvd, Amir Pabarja St, Golhak Road, Dr. Shariati St, Tehran

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2024-07-02, 1403/04/12

Ethics committee reference number

IR.IAU.TMU.REC.1403.168

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.8

ICD-10 code description

Other delirium

Primary outcomes

1

Description

Delirium

Timepoint

Postoperatively up to 24 hours after surgery

Method of measurement

View

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: General anesthesia

Category

Treatment - Drugs

2

Description

Intervention group: Spinal anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Arezo Gholami

Street address

at the beginning of Damavand St, Imam Hossein Square, Tehran

City

Tehran

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1711734365

Phone

+98 21 3334 8036

Email

Wiish1999@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoud Parsania

Street address

Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St, Ayane Blvd, Amir Pabarja St, Golhak Road, Dr. Shariati St, Tehran

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Arezo Gholami

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

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Person responsible for updating data

Contact**Name of organization / entity**

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available