Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of pain control, rate of awakening, and airway quality after simultaneous intravenous administration of fentanyl (5 micrograms per kilogram of body weight) and morphine (5 mg) in posterior spinal fusion surgery patients at Akhtar hospital: A case series study

Protocol summary

Study aim

To evaluate pain control, awakening time, and airway safety after simultaneous intravenous administration of fentanyl and morphine in patients undergoing elective posterior lumbar spinal fusion surgery under general anesthesia.

Design

Prospective, single arm, observational case series conducted at a single center. Sixty participants will be enrolled consecutively. No randomization or blinding will be performed.

Settings and conduct

The study will be conducted in the operating rooms and post anesthesia care unit of the study hospital. Participants will be followed from induction of anesthesia until 24 hours after surgery using a standardized perioperative care protocol.

Participants/Inclusion and exclusion criteria

Adults aged 18 to 65 years with American Society of Anesthesiologists physical status I to III undergoing elective posterior lumbar spinal fusion are eligible. Patients with opioid allergy, severe hepatic or renal impairment, chronic opioid use, substance abuse, severe chronic respiratory disease, pregnancy, breastfeeding, or inability to provide informed consent are excluded.

Intervention groups

All participants receive intravenous fentanyl at 5 micrograms per kilogram and intravenous morphine at 5 milligrams during induction of general anesthesia according to a standardized anesthetic protocol.

Main outcome variables

Pain intensity measured by the Visual Analogue Scale; awakening time from discontinuation of anesthesia to appropriate verbal response; airway safety including oxygen desaturation, hypoventilation, apnea, and need for airway intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260203068755N2**
Registration date: **2026-08-03, 1405/05/12**
Registration timing: **prospective**

Last update: **2026-08-03, 1405/05/12**
Update count: **0**

Registration date

2026-08-03, 1405/05/12

Registrant information

Name

Shayan Kamalfar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2615 7609

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shayankalamfar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-06, 1405/06/15

Expected recruitment end date

2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of pain control, rate of awakening, and airway quality after simultaneous intravenous administration of fentanyl (5 micrograms per kilogram of body weight) and morphine (5 mg) in posterior spinal fusion surgery patients at Akhtar hospital: A case series study

Public title
Effect of Simultaneous Intravenous Fentanyl and Morphine on Pain Relief and Recovery After Lumbar Spine Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults aged 18 to 65 years American Society of Anesthesiologists (ASA) physical status I–III. Scheduled for elective posterior lumbar spinal fusion under general anesthesia. Body weight between 60 and 100 kg. Able to provide written informed consent.

Exclusion criteria:
Known allergy or hypersensitivity to fentanyl, morphine, or other opioids. Severe hepatic impairment (Child–Pugh class C). Severe renal impairment (eGFR <30 mL/min/1.73 m²). Chronic opioid use or opioid dependence. History of substance abuse. Severe chronic respiratory disease (such as chronic obstructive pulmonary disease). Pregnancy or breastfeeding. Inability to provide informed consent.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

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
School of Medicine - Shahid Beheshti University of Medical Sciences (Research Ethics Committee)

Street address
Shahid Chamran Highway- Evin- next to Taleghani Hospital- Medical School- third floor

City
Tehran

Province
Tehran

Postal code
19839-63113

Approval date
2026-06-22, 1405/04/01

Ethics committee reference number
IR.SBMU.MSP.REC.1405.219

Health conditions studied

1

Description of health condition studied
Lumbar degenerative spine disorders requiring elective posterior lumbar spinal fusion surgery

ICD-10 code
M00-M99

ICD-10 code description
Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
Postoperative pain intensity measured using the Visual Analogue Scale.

Timepoint
At admission to the post anesthesia care unit, and at 2, 4, 6, 12, and 24 hours after surgery.

Method of measurement
Pain intensity will be assessed using the ten centimeter Visual Analogue Scale, with scores ranging from zero, indicating no pain, to ten, indicating the worst imaginable pain.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will receive intravenous fentanyl at a dose of 5 micrograms per kilogram of body weight and intravenous morphine at a fixed dose of 5 milligrams simultaneously during induction of general anesthesia. General anesthesia will be induced with propofol and maintained with sevoflurane according to the hospital's standard anesthetic protocol. Standard

postoperative analgesia and prophylaxis for postoperative nausea and vomiting will be provided according to institutional practice.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar hospital

Full name of responsible person

Shayan Kamalfar

Street address

Akhtar Hospital - Azar Dead End - Sharifi Manesh Street - In front of Qaitariya metro - Shariati Avenue - Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziayi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shayan Kamalfar

Position

Associate 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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data regarding anesthesia and outcomes measurements will be available.

When the data will become available and for how long
After data collection completion

To whom data/document is available
Other researchers

Under which criteria data/document could be used
belonging to academic institution

From where data/document is obtainable
researcher's personal email shayankamalfar@sbmu.ac.ir

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

Comments