# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 Jul 2026

## Comparison of Intrathecal Morphine and Fentanyl in Postoperative Pain Management of Spine Surgeries

## Protocol summary

**Study aim**

Comparison of Intrathecal Morphine and Fentanyl in Postoperative Pain of Spine Surgeries

**Design**

This is a two arm double-blinded parallel group randomized trial including two groups of intrathecal morphine and intrathecal fentanyl group. The sample size in each group is 40 and a simple randomization will be used, utilizing a random sequence through random number generator software.

**Settings and conduct**

The study will be conducted at the neurospine surgery department of Shahid Bahonar Hospital, the main referral neurospine center in Kerman, southeast Iran. The participants and outcome assessors will be blinded to the treatment assignment (morphine or fentanyl).

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Candidates for spine surgeries aged between 18 and 85 years and with American Society of Anesthesia (ASA) classification I or II. Exclusion criteria: Pregnant or breastfeeding individuals, patients with a history of allergy to local anesthetic agents, history of cardiac or renal failure, opioid use disorder, uncontrolled blood pressure, body mass index above 40 kg/m2 and a heart rate less than 50 beats/min, patients with spinal cord injuries that could interfere with the pain assessment, patients with incidental durotomy

**Intervention groups**

intrathecal morphine (0.2 mg), intrathecal fentanyl (25 µg)

**Main outcome variables**

The primary outcome will be the postoperative pain in 4, 6, 12, and 18 hours post-surgery. The secondary outcome will be the time interval from the surgical procedure until the patient required supplementary analgesics (specifically, intramuscular ketorolac) in addition to postoperative side effects.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230717058820N1**
Registration date: **2023-11-01, 1402/08/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-01, 1402/08/10**
Update count: **0**

**Registration date**

2023-11-01, 1402/08/10

**Registrant information**

**Name**

Mohammad ehsan Parsa

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 34 3248 1783

**Email address**

ehsanparsa1991@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-11-01, 1402/08/10

**Expected recruitment end date**

2024-01-10, 1402/10/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Intrathecal Morphine and Fentanyl in Postoperative Pain Management of Spine Surgeries

**Public title**
Intrathecal Morphine or Fentanyl for Spine Surgery
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age between 18 to 85 American Society of Anesthesia (ASA) classification I or II Candidates for surgeries of spine Informed consent to enter the study
**Exclusion criteria:**
Pregnancy or breastfeeding at the time of enrollment History of allergy to local anesthetic agents History of cardiac or renal failure Opioid use disorder Uncontrolled blood pressure Body mass index above 40 kg/m2 Preoperative heart rate less than 50 beats/min Spinal cord injuries that could interfere with the pain assessment Incidental intraoperative durotomy
**Age**
From **18 years** old to **85 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
A simple randomization will be used utilizing a computer-generated randomization sequence to assign participants into two groups (morphine or fentanyl). Accordingly, by using random number generator, a random sequence is created including numbers 1 and 2 (so that there are equal numbers in each group as the calculated sample size) and based on that, every patient who meets the criteria of the study will be assigned to one of two study groups.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Both participants and the research team who were in charge of the assessment of the outcomes will be blinded to the treatment assignment. Due to the fact that drug injection is performed during surgery and under anesthesia, patients are automatically blinded to the type of treatment. The person who is responsible for evaluating the outcomes will also be blinded regarding the type of treatment, so that the outcome assessor will not be informed about the type of treatment (morphine/fentanyl). The outcome assessor is a neurosurgery resident who measures the outcomes of the study.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Kerman University of Medical Sciences
**Street address**
Jahad Street
**City**
Kerman
**Province**
Kerman
**Postal code**
7619813159
**Approval date**
2023-01-03, 1401/10/13
**Ethics committee reference number**
IR.KMU.AH.REC.1401.232

## Health conditions studied

**1**

**Description of health condition studied**
Spinal Diseases
**ICD-10 code**
G95.9
**ICD-10 code description**
Disease of spinal cord, unspecified

## Primary outcomes

**1**

**Description**
Postoperative pain intensity
**Timepoint**
4, 6, 12, 18 hours post-operation
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

**1**

**Description**
Time interval from the surgical procedure until the patient required supplementary analgesics
**Timepoint**
From the operation till maximum 18 hours
**Method of measurement**
Timer

**2**

**Description**
Side effects (Postoperative nausea/vomiting, pruritus, dyspnea, respiratory depression)
**Timepoint**
From the operation till maximum 18 hours
**Method of measurement**
Subjective assessment

## Intervention groups

**1**

**Description**
Intervention group: Intrathecal morphine (0.2 mg) which is injected in the L3-L4 or L4-L5 intervertebral space in a single dose at the end of the surgery in the prone position using a 23 needle gauge.
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: Intrathecal fentanyl (25 µg) which is injected in the L3-L4 or L4-L5 intervertebral space in a single dose at the end of the surgery in the prone position using a 23 needle gauge.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Kerman Shahid Bahonar Hospital
**Full name of responsible person**
Mohammad Ehsan Parsa
**Street address**
Valiasr Crossroad, Shahid Bahonar Hospital
**City**
Kerman
**Province**
Kerman
**Postal code**
76137 47181
**Phone**
+98 34 3223 5011
**Email**
ehsanparsa1991@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Abedin Iranpour
**Street address**
Jahad Street
**City**
Kerman
**Province**
Kerman
**Postal code**
7619813159
**Phone**
+98 34 3226 3855
**Email**
a.iranpour@kmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kerman 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**
Kerman University of Medical Sciences
**Full name of responsible person**
Mohammad Ehsan Parsa
**Position**
Neurosurgery Specialist
**Latest degree**
Specialist
**Other areas of specialty/work**
Neurosurgery
**Street address**
Valiasr crossroad, Shahid Bahonar Hospital
**City**
Kerman
**Province**
Kerman
**Postal code**
76137 47181
**Phone**
+98 34 3223 5011
**Email**
ehsanparsa1991@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Mohammad Ehsan Parsa
**Position**
Neurosurgery Specialist
**Latest degree**
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**Phone**
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**Email**
ehsanparsa1991@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Mohammad Ehsan Parsa
**Position**
Neurosurgery Specialist
**Latest degree**
Specialist
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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**
There is no further information
**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**
Yes - There is 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
**Title and more details about the data/document**
N/A
**When the data will become available and for how long**
N/A
**To whom data/document is available**
N/A
**Under which criteria data/document could be used**
N/A
**From where data/document is obtainable**
N/A
**What processes are involved for a request to access data/document**
N/A
**Comments**