Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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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
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
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Person responsible for updating data

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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