

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the mean effect of Remifentanyl, Methadone, and Sufentanil on Pain and Delirium in Patients with spinal surgery

Protocol summary

Study aim

Evaluation of the effect of remifentanyl on pain and delirium in patients with spinal surgery Evaluation of the effect of Methadone on pain and delirium in patients with spinal surgery Evaluation of the effect of Sufentanil on pain and delirium in patients with spinal surgery

Design

A randomized, blinded, sham controlled clinical trial with three parallel groups design of 120 patients with concealed Randomisation sequence carried out at random function from Excel Application

Settings and conduct

Briefly after surgery has been done clinicians inject The Pain Relief Medications in order to manage The Pain after Surgery. In this clinical trial on 120 Patients with Spinal Surgery referred to Imam Khomeini hospital of Ilam, IR from January 2000 to march 2001, we try to evaluate Patients Information of Severity and Duration of Delirium collected from their physical examination and their Pain Score by VAS after Surgery, 6, 12, and 24 Hours later, in three Intervention Groups taking:1-remifentanyl 2-sufentanil 3-Methadone and report the results.

Participants/Inclusion and exclusion criteria

Participants: Patients with Spinal Surgery Inclusion Criteria: Patients with Spinal Surgery taking Remifentanyl Patients with Spinal Surgery taking Sufentanil Patients with Spinal Surgery taking Methadone Exclusion Criteria: Patients with History of Psychological Disorders Patients with History of Drug Addiction Patients with History of Allergic Reaction to Drugs Patients with History of Diabetes Mellitus Patients with History of Kidney Disease

Intervention groups

First Group: Patients with Spinal Surgery taking Remifentanyl Second Group: Patients with Spinal Surgery taking Sufentanil Third Group: Patients with Spinal Surgery taking Methadone

Main outcome variables

Pain Score and Delirium Duration and Severity of Patients With Spinal surgery taking: Remifentanyl;

Sufentanil and Methadone.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221218056854N1**

Registration date: **2023-01-23, 1401/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-23, 1401/11/03**

Update count: **0**

Registration date

2023-01-23, 1401/11/03

Registrant information

Name

Hamid Reza Zanj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3422 4443

Email address

hamidzanji1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

Sciences

Street address

Yas building 4th floor. Golha Sq. Ilam. IR Iran

City

Ilam

Province

Ilam

Postal code

6931371549

Approval date

Ethics committee reference number

IR.MEDILAM.REC.1401.173

Health conditions studied

1

Description of health condition studied

multiple fractures of spine, level unspecified

ICD-10 code

T08

ICD-10 code description

- Fracture of spine, level unspecified

Primary outcomes

1

Description

Delirium Severity and Duration

Timepoint

After Spinal Surgery, 6, 12, and 24 Hours After Surgery

Method of measurement

Physical Examination

2

Description

Four Main Delirium Features

Timepoint

After Spinal Surgery, 6, 12 and 24 Hours After Surgery

Method of measurement

CAM-ICU(Confusion Assessment Method for the Intensive Care Unit) Questionnaire

3

Description

Pain Intensity Score

Timepoint

After Spinal Surgery, 6, 12 and 24 Hours After Surgery

Method of measurement

Visual Analog Scale

Intervention groups

1

Description

Intervention group: patients with spinal surgery whom received Remifentanil Infusion as Remifentanil Hydrochloride I.V. 1mg, sold under the brand name EPAXIR, Exir Pharmaceutical Co. with Dosage: 0.05 to 2 µg/kg Injected at the surgery time and 30 minutes after anesthesia

Category

Rehabilitation

2

Description

Intervention group: patients with spinal surgery whom received Sufentanil Infusion as Sufentanil Citrate I.V. 50µg sold under the brand name SUFIJECT, Aburaihan Pharmaceutical Co. with Dosage: 2.5 to 15 µg/kg Injected at the surgery time and 30 minutes after anesthesia

Category

Rehabilitation

3

Description

Intervention group: patients with spinal surgery whom received Methadone Infusion as Methadone Hydrochloride I.V. 5mg/ml sold under the brand name Methadone, Darou Pakhsh Pharmaceutical Co. with Dosage: 20mg Injected at the surgery time and 30 minutes after anesthesia

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Hedaiat Heidarizad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

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sci@medilam.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Hamidreza Zanj

Position

Medical Student, Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Ilam University of Medical Sciences

Full name of responsible person

Lida Nouri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available