

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intrathecal morphine analgesic effect after post operative lumbar vertebral fusion surgery in addict and non-addict patients admitted in Ahwaz Golestan hospital's neurosurgery ward.

Protocol summary

Summary

Objectives: Measurement of analgesic effect of intrathecal morphine in lumbar spine surgery and compare of their side effects with systemic morphine administration Design: In admission the patients randomly will be divided to 4 groups (addict case & control and non addict case & control). Patients in case groups (addict, non addict) will be injected with 0.3 mg intrathecal morphine before terminating of spinal fusion surgery. Patients of control group will not receive any medication. Pain of patients measured with visual analogue score (with 10 CM no -calibrated ruler) in 0(before anesthesia), 4, 8,12,18,24 hours after surgery. In ward if the pain of patients exceeds 50/100 will injected 1 mg IV slowly morphine When the end of surgery to the first intravenous injection of morphine for each patient will be measured and recorded. And all side effects (nausea, vomiting, pruritus, headache, urinary retention and respirator suppression) will be recorded throughout the study period. Then data will be analyzed with SPSS. For data analyzes descriptive statics (mean, standard deviation), charts will be used, and also paired T-test will be used to compare the pain level of patients in two state. Independent T-test and chi-square will be used for comparison. $P \leq 0.05$ will be statistically significant. Main outcome measures variables: Post operative pain score and mean intravenous morphine use. inclusion criteria: All patients with lumbar vertebral fracture that candidate to surgery. exclusion criteria: patients with life threatening multiple trauma (eg: sever chest or abdominal); patients with severe medical disorder (eg: cardiopulmonary, renal failure, hepatic failure); patients with history of morphine or opiate allergy; pregnant patients; patients under 15 years old; patients with addiction to other substance such as: crack, ecstasy, cannabinoid, marijuana, other illicit drugs; patients with pre or post operative neurologic

deficit

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012065325N1**

Registration date: **2011-09-03, 1390/06/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-03, 1390/06/12

Registrant information

Name

Reza Bahrami Ilkhchi

Name of organization / entity

Ahwaz Jondishapour University

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3032

Email address

bahrami.r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Ahwaz Jondishapour University

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2011-04-04, 1390/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intrathecal morphine analgesic effect after post operative lumbar vertebral fusion surgery in addict and non-addict patients admitted in Ahwaz Golestan hospital's neurosurgery ward.

Public title

Pain in spine surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with lumbar vertebral fracture that candidate to surgery. exclusion criteria: patients with life threatening multiple trauma (eg: sever chest or abdominal); patients with severe medical disorder(eg: cardiopulmonary, renal failure ,hepatic failure); patients with history of morphine or opiate allergy; pregnant patients; patients under 15 years old; patients with addiction to other substance such as: crack, ecstasy, cannabinoid, marijuana, other illicit drugs; patients with pre or post operative neurologic deficit.

AgeFrom **15 years** old to **75 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Jondishapour Medical University

Street address

Vice chancellor for research, Jondishapour University,

Golestan st

City

Ahwaz

Postal code**Approval date**

2010-12-31, 1389/10/10

Ethics committee reference number

eth020

Health conditions studied**1****Description of health condition studied**

Lumbar spine fracture

ICD-10 code

S32.0

ICD-10 code description

Fracture of lumbar vertebra

Primary outcomes**1****Description**

Rate of Morphine used

Timepoint

0.4.8.12.18.24 hour post operation

Method of measurement

In data collection form

Secondary outcomes**1****Description**

Patient pain

Timepoint

0.4.8.12.18.24 hour post operatin

Method of measurement

Visual analog score

Intervention groups**1****Description**

Addict case group:0.3 mg intratechal morphine injection for preemptive analgesia

Category

Treatment - Drugs

2**Description**

Addict control group:no intervention Non addict control groups:no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital neurosurgery ward

Full name of responsible person

Dr.Reza Bahrami Ilkhchi

Street address

Ahwaz Jondishapour University of Medical Science

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahwaz Jondishapour
University of Medical Sciences

Full name of responsible person

Dr.Masud Zeinali

Street address

Ahwaz Jondishapour Medical University

City

AhWaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Ahwaz Jondishapour
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahwaz JondiShapour Medical University

Full name of responsible person

Dr.Reza Bahrami Ilkhchi

Position

Neurosurgery resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty