

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of analgesia and side effects in Fentanyl epidural and Fentanyl, Bupivacaine epidural after spinal surgery Spondylolisthesis surgery and Spinal fixation Spondylolisthesis surgery and Spinal fixation

Protocol summary

2014-06-27, 1393/04/06

Summary

The objective of this study is to compare of analgesic effect and side effects in Fentanyl epidural and Fentanyl - Bupivacaine epidural after Spondylolisthesis surgery and Spinal fixation. Inclusion criteria: Ninety patients aged 18 to 75 years underwent Spondylolisthesis and spinal fixation surgery and had not mental disorder, hepatic or renal failure and addiction. Exclusion criteria: Dural damage; exclusion of epidural catheter; Patient dissatisfaction. Patients with random block classification were divided into 3 groups. First group: intravenous Morphine if was needed (control group), second group: epidural Fentanyl and third group: Epidural Fentanyl and Bupivacaine. In both groups epidural Fentanyl and epidural Fentanyl, Bupivacaine group, surgeon put an epidural catheter in the epidural space at the end of operation. These drugs infusion after patient arrival to recovery unit. For primary pain control Apotel 1 gram in 100 cc normal saline will be infused 20 minutes prior to the end of surgery, then repeat every 6 hours. Blood pressure, Heart rate, Respiratory rate and pain score were monitored and documented when patient were transferred from recovery unit to the section and 4 hours after surgery, then every 6 hours up to 24 hours. Our goal is to get the best postoperative analgesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031016917N1**
Registration date: **2014-06-27, 1393/04/06**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Ali Ashraf

Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesia and side effects in Fentanyl epidural and Fentanyl, Bupivacaine epidural after spinal surgery Spondylolisthesis surgery and Spinal fixation Spondylolisthesis surgery and Spinal fixation

Public title

Relevance analgesia and side effects with Fentanyl epidural and Fentanyl, Bupivacaine epidural after spinal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18 to 75 years old; patients undergoing Spondylolisthesis surgery and Spinal fixation; American Society of Anesthesiologists (ASA) I, II, III
Exclusion criteria: If the Dural be damaged; Patient dissatisfaction

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Guilan university of Medical Sciences

Street address

Namjoo street

City

Rasht

Postal code

4193893345

Approval date

2014-05-12, 1393/02/22

Ethics committee reference number

1930075301

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

Relevance analgesia and side effects with Fentanyl epidural and Fentanyl - Bupivacaine epidural after spinal surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

when patient were transferred to the section from recovery unit then every 6 hours to 24 hours

Method of measurement

Visual analogous score

2**Description**

Hypotension

Timepoint

when patient were transferred to the section from recovery unit then every 6 hours to 24 hours

Method of measurement

mmHg, Saadat company

Secondary outcomes

empty

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

Intervention 1) For primary pain control Apotel 1 gram in 100 cc normal saline will be infused 20 minutes prior to the end of surgery, then repeat every 6 hours. . If VAS is more than 4 , we inject 1 mg intravenous of morphine .

Category

Treatment - Drugs

2**Description**

Intervention 2) Surgeon put an epidural catheter in the L3-L4 epidural space at the end of operation. Epidural pump with 100 microgram Fentanyl added to 98 cc normal saline 3-5 ml/h after patient arrival to recovery unit will be infused. Primary pain control Apotel 1 gram in 100 cc normal saline, 20 minutes prior to the end of surgery will be infused for all of patients, and then repeat every 6 hours. If VAS is more than 4, we inject 1 mg intravenous of Morphine.

Category

Prevention

3**Description**

Intervention3) The Surgeon put an epidural catheter in the L3-L4 epidural space at the end of operation. Epidural pump with 98 cc normal saline add to 100 microgram Fentanyl and Bupivacaine 0.125 % (24 ml

Bupivacaine 0.5% add to 72 ml normal saline), 3–5 ml/h will be infused after patient arrival to recovery unit.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Ali Ashraf

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

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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

Vice chancellor for research of Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

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Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work

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Hedieh Nemati

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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