Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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 Bupivacain.In both groups epidural Fentanyl and epidural Fentanyl, Bupivacain 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

2014-06-27, 1393/04/06

Registrant information

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Guilan University of Medical Sciences
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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 to100 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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Shahid beheshti Highway

City
Rasht

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

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Position
Anesthesiologist, Assistant Professor

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