

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison the effect of continuous injection of bupivacaine via intra incisional catheter versus PCA morphine pump on reduction of postoperative pain intensity in thoracic and lumbar spine fixation surgery

Protocol summary

Study aim

Comparison the effect of continuous injection of bupivacaine via intra incisional catheter application versus PCA morphine pump on reduction of postoperative pain intensity in thoracic and lumbar spinal fixation surgery

Design

Not blinded Randomized Clinical Trial

Settings and conduct

No blinding was performed in this study. To control postoperative pain in patients undergoing thoracic spine fixation surgeries in Chamran hospital, Shiraz, the surgeon puts a Intra incisional catheter for infusion of bupivacaine 6 ml / h until 24 h postoperatively and in control surgeon does not insert a multi-pore catheter in the fascia .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidate for surgical fixation of the thoracic and lumbar spine ,the age range-40 years (ASA1or2) ,The mental ability to collaborate in the study. Exclusion criteria: Uncontrolled seizure, Depression, Localized surgical site infection, Rupture and repair of dura, Severe coagulation disorder, drug abuse or dependence, Drug Allergy, Patients with psycho-somatic pains

Intervention groups

Intervention group: surgeon puts a Intra incisional catheter at end of surgery ,which is connected to an elastomeric pump and infusion of bupivacaine (0.25% Bupivacaine, Mylan, A.S.A., France) will begin. after bolus injection of 30 ml of bupivacaine 0.25% , 6 ml / h will begin until 24 h postoperatively. Control group: The surgeon dose not put a Intra incisional catheter but intravenous morphine (Aburaihan Pharmaceutical Co.Iran) will be done with intravenous infusion pump until 24 h postoperatively.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003213N7**

Registration date: **2019-11-07, 1398/08/16**

Registration timing: **prospective**

Last update: **2019-11-07, 1398/08/16**

Update count: **0**

Registration date

2019-11-07, 1398/08/16

Registrant information

Name

Arash Farbood

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison the effect of continuous injection of bupivacaine via intra incisional catheter versus PCA morphine pump on reduction of postoperative pain intensity in thoracic and lumbar spine fixation surgery

Public title
The effect of continuous infusion of bupivacaine via intra incisional catheter on reduction of pain intensity after surgery in spinal fixation surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients candidate for surgical fixation of the thoracic and lumbar spine (TLIF) The age range is 75-40 years (ASA = 1 or 2) The mental ability to collaborate in the study
Exclusion criteria:
Uncontrolled seizure Depression Localized surgical site infection Rupture and repair of dura, Severe coagulation disorder Abuse and drug dependence Drug Allergy Patients with psycho-somatic pains

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization:Patients will be randomized based on the randomization chart which is derived from from Randomization.org.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2018-02-24, 1396/12/05

Ethics committee reference number

IR.SUMS.MED.REC.1396.125

Health conditions studied

1

Description of health condition studied

Spinal surgery

ICD-10 code

M43.25

ICD-10 code description

Fusion of spine, thoracolumbar region

Primary outcomes

1

Description

Pain

Timepoint

If the patient is consciousness: every 15 minutes (15-30-45-60 minute intervals) pain will be assessed in the recovery room.During the first 6 hours, every hour, at the second 6 hours every 2 hours and at the 12 hours later every 4 hours, pain will be assessed in the ward.

Method of measurement

Numeric Rating Scale (NRS)

Secondary outcomes

1

Description

First analgesic requirement based on minutes of the patient's presence in recovery room and ward

Timepoint

First analgesic requirement (based on minutes) after the patient's presence in recovery room every 15 minutes for an hour, and then in the ward every hour for 6 hours and then every 2 hours to 12 hours and then every 4 hours to 24 hours post operation.

Method of measurement

Observation

2

Description

Total morphine consumption

Timepoint

Total morphine consumption during postoperative first 24 h

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: The surgeon puts a Intra incisional catheter (Infiltra long manufacturing company. Pajunk of Germany) before closing the surgical wound in the basement of the fascia. After insertion of the catheter, the catheter will be connected to an elastomeric pump and after injection of bolus dose (30 ml Bupivacaine 0.25%) (Bupivacaine, Mylan, A.S.A, France) infusion of bupivacaine 0.25% with rate 6 ml per hour until 24 h will begin.

Category

Prevention

2

Description

control group: The surgeon does not insert a Intra incisional catheter (Infiltra long manufacturing company. Pajunk of Germany) before the surgical wound is placed under the fascia layer. After the bolus injection of 2 ml of morphine sulfate (Aburaihan Pharmaceutical Co. Iran,) the pump settings are as follows: 20 ml of morphine sulfate at a concentration of 0.5 mg / ml in normal saline solution infused with infusion pump. Minimum injection interval: 7 minutes, maximal injection every 4 hours: 40 ml, and continued for 24 hours.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital, Shiraz

Full name of responsible person

Vahid Parvin

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Shahid Chamran Hospital, Chamran Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Parvin

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Position
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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