Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of continuous infusion of bupivacaine through intra-incisional catheter with control group for postoperative pain relieve in patients with intertrochanteric fracture

Protocol summary

Study aim
Comparison of the effect of continuous infusion of bupivacaine through intra-incisional catheter with control group for postoperative pain relieve in patients with intertrochanteric fracture

Design
Parallel Randomized Controlled Clinical Trial

Settings and conduct
At the end of the operation in the intervention group, an intra-incisional catheter will be placed under the fascial layer by surgeon, and after injection of 30 ml 0.25% bupivacaine it will be attached to an elastomeric pump containing 0.25% bupivacaine running 6 ml per hour. In control group no catheter will be placed. In both groups, an IV PCA morphine (0.5 mg/ml) pump will be run by the following setup: 2 ml bolus dose, 7 minutes lockout interval, no background infusion

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients who scheduled to undergo hip nailing surgery and can tolerate surgery under spinal anesthesia, ASA I-II, 50-85 years of age. Exclusion Criteria: Uncontrolled seizure, Local infection, coagulopathy, thrombocytopenia, history of hepatic and renal functional impairment, narcotic addiction, allergy to drugs which are going to be used in this study, history of psychosomatic pain, psychiatric diseases, Diabetic neuropathy, 2nd and 3rd degree A-V block.

Intervention groups
In intervention group intra-incisional catheter will be placed for continuous bupivacaine infusion. Patients in both groups will be attached to IV morphine PCA pumps for better pain relieve.

Main outcome variables
Pain intensity during the first postoperative day; total morphine administered during the first postoperative day

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100127003213N8**
Registration date: **2020-03-16, 1398/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-16, 1398/12/26**
Update count: **0**

Registration date
2020-03-16, 1398/12/26

Registrant information

Name
Arash Farbood

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of continuous infusion of bupivacaine through intra-incisional catheter with control group for postoperative pain relieve in patients with intertrochanteric fracture

Public title
Effect of intraincisional bupivacaine infusion in intertrochanteric fracture

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who scheduled to undergo hip nailing surgery and can tolerate surgery under spinal anesthesia American Society of Anesthesiologists (ASA) I-II 50-85 years of age

Exclusion criteria:
Uncontrolled seizure Local infection Coagulopathy Thrombocytopenia History of hepatic and renal function impairment narcotic addiction Allergy to drugs which are going to be used in this study History of Psychosomatic pain Psychiatric diseases Diabetic neuropathy 2nd and 3rd degree A-V block

Age
From **50 years** old to **85 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into intervention and control groups by block randomization using randomization.com website. This will randomly generate a sequence of 12 blocks, 4 patients in each. The name of the patients' group will be concealed in separate envelops which are identified by consecutive numbers related to the patient's entrance to the study.

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
2019-04-27, 1398/02/07

Ethics committee reference number
IR.SUMS.MED.REC.1398.099

Health conditions studied

1

Description of health condition studied
Femur fracture

ICD-10 code
S72.14

ICD-10 code description
Intertrochanteric fracture of femur

Primary outcomes

1

Description
Pain intensity

Timepoint
Every 15 minutes after surgery (15, 30, 45, 60 minutes) in recovery room, and every 2 hours after transfer to ward .

Method of measurement
Numerical Rating Scale of pain

2

Description
total morphine administration

Timepoint
total dose during the first postoperative 24 hours

Method of measurement
dose summation reported in milligrams

Secondary outcomes

1

Description
Patient’s global satisfaction

Timepoint
Discharge from the ward

Method of measurement
A 5-point Likert scale: completely satisfied (= 5), partially satisfied (= 4), neutral (= 3), partially dissatisfied (= 2) and completely dissatisfied (= 1)

2

Description
Ease of ambulation
Timepoint
During admission
Method of measurement
Cumulated Ambulation Score

3

Description
Time to first request for analgesia
Timepoint
Time to first request, measured from termination of the procedure and recovery room entry
Method of measurement
minute

4

Description
Drug side effects (nausea & vomiting, respiratory depression, urinary retention, drowsiness, pruritus, hypotension, tinnitus)
Timepoint
Every four hours for 24 hours
Method of measurement
Occurrence frequency

Intervention groups

1

Description
Interventions group 1:At the end of the surgery an intra-incisional catheter (Infiltralong 600, PAJUNK, Geisingen, Germany) will be placed subfascially which will be connected to a 100 mL elastomeric pump, contained 0.25% bupivacaine by the rate of 6 ml per hour, after a 30 mL bolus dose of 0.25% bupivacaine (Bupivacaïne® Mylan, 100 mg/20 ml vial, Delpharm, France). The intra-incisional catheter will be disconnected after 36 hours.
Category
Prevention

2

Description
Control group:The surgeon does not insert a Intra incisional catheter(Infiltralong 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. infusing morphine, intravenously.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Sanaz Abbasi
Street address
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 Yones Ghasemi
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
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sacrc@sums.ac.ir
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

Sanaz Abbasi

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

Arash Farbood

Position

Anesthesiologist/Pain Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our policies.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available