

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1233 7636

##### Email address

farboda@sums.ac.ir

##### 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



### 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 (Bupivacaine® 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 an 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

#### City

Shiraz

#### Province

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#### Phone

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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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### 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  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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