

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of patient education about patient-controlled analgesia pump before Spinal column surgery on their pain management after surgery

#### Protocol summary

##### Study aim

The purpose of this study is evaluating the effect of patient education about patient-controlled analgesia pump before surgery on their pain management after Spinal column surgery.

##### Design

In this study, 60 patients candidate for elective spinal column surgery, that have inclusion criteria for study, will be hospitalized to Fatemi Hospital in Ardabil, will be selected by accessible sampling, then divided into two groups of intervention and control by simple randomization. Blinding will not be done.

##### Settings and conduct

The researcher will be present at the Neurosurgery Department of Dr. Fatemi Hospital in Ardebil at 19:00 hour. She will identify the eligible patients by studying the patient records. Participants will be entered into the study after goal and method of the research explanation, and written consent. The Neurosurgeon ward includes 30 beds in both women and men. According to the routine, patients after surgery come back to the same bed at the admission time. The same night (before surgery), for all participants will be completed demographic forms, pre-intervention evaluations, and training about using of analgesic pump. Surgical procedures, anesthetist, surgeon, general anesthetic procedures will be similar for all subjects. Analgesic pump is improvised in recovery ward, then routine training is done. The dominant protocol is the use of an analgesic pump consisting of 30 cc fentanyl in 70 cc normal saline (the total contents of the pump is 100 cc). According to the routine, the drugs in the pump are continuously injected with 4CC/h speed. Also, patient can inject 15 micrograms drug every 15 minutes as blousy. The pump is used for 48 hours, and if necessary, it can be recharged. How to use of PCA pump, causes of postoperative pain, how to manage and control pain, the side effects of PCA and the excessive use of analgesia will be taught to the intervention group by the researcher.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who have been elective spinal column surgery; hospitalized at least one night before surgery; have reading and writing skills; ability to communicate verbally; Age range between 18 to 60 years old; received general anesthesia for surgery. Exclusion criteria: allergic reactions to any components of analgesia pump; history of coagulation disorders; Transfer to other wards; Patient death; reasons; receiving another analgesic agents concurrent with PCA pump; History of addiction; history of using analgesic pump.

##### Intervention groups

Patients in intervention group in addition to routine education in recovery ward, will be received a 15-minutes individual education session using a sample PCA pump. After the training, we will ask the patient to explain how to use the pump. Also, patients will be received a brochure that containing of duplicate and additional information about set of pump. Before the start of training, patients' knowledge about the PCA pump is evaluate using the "Patient Knowledge about the PCA Pump" questionnaire. The control group does not receive any preoperative training. They only will be received the post-surgical routine training by anesthesia nurses at the recovery unit. The patient's knowledge of the PCA pump is measured using the "Patient Knowledge on the PCA Pump" questionnaire.

##### Main outcome variables

Pain severity based on NRS

#### General information

##### Reason for update

##### Acronym

PCA

##### IRCT registration information

IRCT registration number: **IRCT20170123032129N5**

Registration date: **2018-03-06, 1396/12/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-06, 1396/12/15**

Update count: **0**

**Registration date**

2018-03-06, 1396/12/15

**Registrant information**

**Name**

Azim Azizi

**Name of organization / entity**

Hamadan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 81 3838 0150

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-01-21, 1396/11/01

**Expected recruitment end date**

2018-07-21, 1397/04/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of patient education about patient-controlled analgesia pump before Spinal column surgery on their pain management after surgery

**Public title**

Effects of patient education on pain management

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients who have elective Spinal column surgery All patients who have the ability to communicate verbally All patients who have been hospitalized at least one night before surgery All patients do not have a history of substance abuse and Opioid drug addiction Participants do not have a history of using patient-controlled analgesia pump All patients who have received general anesthesia

**Exclusion criteria:**

Patients who have emergency Spinal column surgery All patients have a history of substance abuse and Opioid drug addiction All patients who have allergic reactions to any components of analgesia pump All patients who are receiving analgesic agent other than pain control pump

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, they are available to qualified patients and then randomly assigned to two groups of test and control. Based on the lottery, patients admitted to the control group and the days of the intervention in the intervention group.

**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 Hamadan University of Medical Sciences

**Street address**

Hamadan University of Medical Sciences, Ayatollah Kashani Blvd, Hamadan.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517619651

**Approval date**

2017-08-29, 1396/06/07

**Ethics committee reference number**

IR.UMSHA.REC.1396.607

**Health conditions studied**

1

**Description of health condition studied**

Fracture of spine, level unspecified

**ICD-10 code**

T08

**ICD-10 code description**

Fracture of spine, level unspecified

## 2

### **Description of health condition studied**

Fracture of lumbar spine and pelvis

### **ICD-10 code**

S32

### **ICD-10 code description**

Fracture of lumbar spine and pelvis

## **Primary outcomes**

### 1

#### **Description**

Pain severity

#### **Timepoint**

2, 4 and 24 after surgery

#### **Method of measurement**

Numerical rating scale

## **Secondary outcomes**

### 1

#### **Description**

Pain control quality

#### **Timepoint**

24 hours after surgery

#### **Method of measurement**

APS-POQ-R(American Pain Society Patient Outcome Questionnaire )

### 2

#### **Description**

severity of nausea

#### **Timepoint**

2,4 and 24 hours after surgery

#### **Method of measurement**

VAS(visual analog scale)

### 3

#### **Description**

times of nausea

#### **Timepoint**

2,4 and 24 hours after surgery

#### **Method of measurement**

subjective

### 4

#### **Description**

times of vomiting

#### **Timepoint**

2,4 and 24 hours after surgery

#### **Method of measurement**

visual

### 5

#### **Description**

blood pressure

### **Timepoint**

2,4 and 24 hours after surgery

### **Method of measurement**

sphygmomanometer

### 6

#### **Description**

sedation

#### **Timepoint**

2,4 and 24 hours after surgery

#### **Method of measurement**

Ramsy scale

### 7

#### **Description**

Drug dose used

#### **Timepoint**

24 hours after surgery

#### **Method of measurement**

measurement of drug residual dose

### 8

#### **Description**

awareness of patients about PCA

#### **Timepoint**

2,4 and 24 hours after surgery

#### **Method of measurement**

A questionnaire with 7 questions about patient awareness about the PCA pump

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients in intervention group in addition to routine education in recovery ward will receive a 15-minutes individualized face to face educational session using a PCA pump. Patient is wanted to explain the usage of pump to researcher. Also, patients will receive a brochure containing additional information.

#### **Category**

Other

### 2

#### **Description**

Control group: Routine education in recovery ward

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Doctor Fatemi Hospita

**Full name of responsible person**

Mahnaz Khatibian

**Street address**Doctor Fatemi Hospital, Imam Khomeini Street,  
Shariati Square, Ardabil.**City**

Ardabil

**Province**

Ardabil

**Postal code**

5614733775

**Phone**

+98 45 3323 2520

**Email**

f.salehzadeh95@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**Hamadan University of Medical Sciences, Mardom  
Crossroad**City**

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+98 81 3838 1646

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s-bashirian@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Mahnaz Khatibian

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Salehzadeh

**Position**

دانشجو

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Proposal, anonymous written consent, data file, research tools

**When the data will become available and for how long**

Six months after the result publication

**To whom data/document is available**

All the individual's who are requesting.

**Under which criteria data/document could be used**

There is no specific condition for receiving unrecognizable data.

**From where data/document is obtainable**

Fatemeh Salehzadeh Tel: +989370459271 e-mail:  
f.salehzadeh95@gmail.com

**What processes are involved for a request to access data/document**

The applicant must send his/her written request via e-mail. After control and confirmation by the research's supervisor, information will be sent to the requestor.

**Comments**