Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Effect of patient education about patient-controlled analgesia pump before Spinal culumn 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 culumn surgery.

Design

In this study, 60 patients candidate for elective spinal culumn 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 culumn 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
a.azizi@umsha.ac.ir

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 culumn surgery on their pain management after surgery

Public title
Effects of patient education on pain managment

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have elective Spinal culumn 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 culumn 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 Sciencesو Mardom Crossroad
City
Hamadan
Province
Hamadan
Postal code
6517619651
Phone
+98 81 3838 1646
Email
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
Street address
Hamadan University of Medical Sciences, Mardom Crossroad
City
Hamadan
Province
Hamadan
Postal code
6517619651
Phone
+98 81 3838 0572
Email
mahnaz.khatiban@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mahnaz Khatiban
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Hamadan University of Medical Sciences, Mardom Crossroad
City
Hamadan
Province
Hamadan
Postal code
6517619651
Phone
+98 81 3838 0572
Email
m-khatiban@umsha.ac.ir

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

Street address

Hamadan University of Medical Science, Mardom Crossroad

City

Hamadan

Province

Hamadan

Postal code

6517619651

Phone

+98 81 3838 0572

Email

f.salehzadeh95@gmail.com

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