Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the effect of family-oriented educational intervention on post-operative pain in patients undergoing orthopedic surgery (upper or lower limb)

Protocol summary

Summary

This study aims to investigate the effect of family-oriented educational intervention on post-operative pain after orthopedic surgery (upper or lower limbs).In this quasi-experimental clinical trial study (with control group), the study population will be patients undergoing orthopedic surgery hospitalized in Ayatollah Mousavi medical educational center affiliated by Zanjan University of Medical Sciences. In this regard, 50 patients undergoing orthopedic surgery will be included in this study through using convenience sampling method. The experimental group (n = 25) and the control group (n = 25), will receive designed intervention and routine care respectively. The designed intervention will be consisted of educating the patient and the family members about theoretical aspects of post-operative pain, introducing non-pharmacological pain management procedures, encouraging patients and family members to express fears and beliefs about the side- effects of sedative drugs and telling patients how to use the visual analog scale (VAS) to assess pain before requesting sedative drugs. In order to assess the effect of designed intervention, visual analog scale (VAS) will be applied to assess the severity of post-operative pain up to three days after surgery. Inclusion criteria of this study are undergoing elective orthopedic surgery; being older than 18 years; having a healthy mental state; no history of drug abuse; and being accompanied by a family member during hospitalization. The study exclusion criteria will be lack of patients and their family’s cooperation during the intervention; decreased level of patient's consciousness after surgery; patient discharge or patient death; drug abuse in post-operative time and transferring the patients to another hospital. The post-operative pain is the main outcome of this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102816843N3**
Registration date: **2017-06-10, 1396/03/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-10, 1396/03/20

Registrant information

Name

Nasrin Bahraminejad

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Zanjan University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessing the effect of family-oriented educational intervention on post-operative pain in patients undergoing orthopedic surgery (upper or lower limb)

Public title
The effect of family educational on post operative pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Undergoing orthopedic surgery (upper or lower limbs); being older than 18 years; desire to participate in the study; ability to speak and read in Persian; healthy mental status; healthy visual status to see and understand VAS tool; being accompanied by a family member during hospitalization period. Exclusion criteria: history of previous surgeries; history of mental illnesses; using psychotropic drugs; history of drug abuse.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
quasi-experimental double blind clinical trial study

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi blvd
City
Zanjan
Postal code
Approval date
2015-06-07, 1394/03/17
Ethics committee reference number
ZUMS.REC.1394.317

2

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi blvd
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Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
00982433420670

Health conditions studied

1

Description of health condition studied
Post operative pain
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Post operative pain
Timepoint
Every one hour during the waking time, for 2-3 days after surgery
Method of measurement
VAS (Visual analog Scale)

Secondary outcomes

1

Description
Anexity
Timepoint
Before intervention and after second educational session
Method of measurement
Spielberger tool

Intervention groups

1

Description
Intervention group: Two face to face educational

sessions with participation of family members, patients and nurses will be held. The first educational session will be conducted before and during surgery including educating the patients and a member of the family about post-operative pain physiology, non- pharmacological pain control intervention and pain assessment tools; Informing patients and family members on how to participate in post-operative pain management and evaluating the non- pharmacological pain control strategies effect, employed by patients in post -operative period. The second training session will be conducted after the surgery when the patients will regain consciousness, and during this session the following interventions will be done: Assessing, strengthening and encouraging the non-pharmacological strategies used by the patient

Category

Behavior

2

Description

Control group: Control group will receive routine care and pain will be merely assessed for 3 days after the surgery similar to intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and treatment center of Ayatollah Mousavi

Full name of responsible person

Monireh Rahmani

Street address

Educational and treatment center of Ayatollah Mousavi, Gavazang road

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Zanjan University of Medical Sciences

Full name of responsible person

Dr Vakili

Street address

Zanjan University of Medical Sciences, Azadi square

City

Zanjan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Monireh Rahmani

Position

MS student in critical care nursing

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty