

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

City

Zanjan

Postal code**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**

Anxiety

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