Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial the effect of before-anesthesia education on crusher surgery through the skin day anxiety, by spinal anesthesia compared with patients with routine care

Protocol summary

Summary

The aim of this study is to evaluate the effect of before-anesthesia education on the level of anxiety in patients. The level of anxiety as the main variable was measured before education and on the morning of surgery using the Spielberger questionnaire. Education was provided to the intervention group according to Miller, 2011, the authoritative source book on anesthesia. The study population included all patients referred to Jahrom Peymanieh hospital for crusher surgery through the skin with spinal anesthesia. Patients with chronic pains and cancer, hearing or verbal impairment, mental and psychological problems, anti-anxiety drug users and health care workers were excluded from the study. The sample size was estimated to be 80 people. Patients were divided randomly, yet systematically, into control group (group I) and intervention group (group II) before surgery. In the first group anesthesia technician- without any intervention -filled out the questionnaire by the patient the day before surgery and on the morning of surgery. The second group received educations and consulting interventions by anesthesia technician in this way that the technician went to the patient's bedside the day before surgery and at first filled out the questionnaire by the patient, then he familiarized the patient with the type of anesthesia and surgical procedure and responded to all questions of the patient. Besides, he explained about the intended anesthetic technique and surgery complications. On the morning of surgery, the technician again met the patient in the operating room and filled out the questionnaire by the patient before surgery. All Patients had informed consent to participate in the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071814049N1**
Registration date: **2016-02-10, 1394/11/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-10, 1394/11/21

Registrant information

Name

Ali Abbasi Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Jahrom University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial the effect of before-anesthesia education on crusher surgery through the skin day anxiety, by spinal anesthesia compared with patients with routine care

Public title
The effect of before-anesthesia education on surgery day anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: They include all patients who are to undergo crusher surgery through the skin in Peymanieh hospital affiliated with Jahrom University of Medical Sciences; spinal anesthesia can be performed for them; Informed consent to participate in this study. Exclusion criteria: education under primary school; chronic pains and cancer; Hearing or speech impairment; lack of mental and psychological health; chronic use of painkillers and narcotics; Unstable hemodynamic status; expressing disagreement for continuing the research; health care workers; anti-anxiety drug users; Incomplete filling of the questionnaire
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Ethic Committee of Jahrom University of Medical Sciences
Street address
School of medicine, Motahhari Blvd, Jahrom
City
Jahrom
Postal code

Approval date
2014-02-10, 1392/11/21
Ethics committee reference number
2766/د/پ

Health conditions studied

1

Description of health condition studied
The level of anxiety after educating patient
ICD-10 code
F48.8
ICD-10 code description
Other specified neurotic disorders

Primary outcomes

1

Description
Anxiety
Timepoint
The day before and the morning of surgery
Method of measurement
Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the Control group: anesthesia technician- without any intervention -filled out the questionnaire by the patient the day before surgery and on the morning of surgery
Category
N/A

2

Description
Intervention group: Anesthesia technician went to the patient's bedside the day before surgery and filled out the questionnaire by the patient, before offering educations, then he familiarized the patient with the type of anesthesia and surgical procedure and responded to all questions of the patient. Besides, he explained about the intended anesthetic technique and surgery complications. On the morning of surgery, the technician again met the patient in the operating room and filled out the questionnaire by the patient before surgery.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Peymanieh Hospital
Full name of responsible person
Farzaneh Mehran
Street address
Nakhlestan Blvd, Jahrom
City
Jahrom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Jahrom University of Medical Sciences
Full name of responsible person
Solh Ju Kavos
Street address
Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom Jahrom
City
Jahrom
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, Jahrom 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
Jahrom University of Medical Sciences
Full name of responsible person
Farzaneh Mehran
Position
Anesthesia Undergraduate Student
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Abbasi Jahromi Ali
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Faculty member
Other areas of specialty/work
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Person responsible for updating data

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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