Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The Effect of Patient Preparation by Multimedia Method on Anxiety, Pain, and Consumption of analgesic after Vitrectomy surgery.

Protocol summary

Study aim
Determining The Effect of Patient Preparation by Multimedia Method on Anxiety,Pain,and Consumption of analgesic after Vitrectomy

Design
Clinical trail with control group with non-parallel groups, double blind, randomized block, with evaluation of results

Settings and conduct
The information is collected by researcher assistant. In order to blind the study, the researcher assistants and statistical advisers are not informed about the allocation of patients in the control or intervention groups. The method of conducting the research: clinical trial research implementation environment: Khalili Hospital of Shiraz Case study: Patients who are the candidates of vitrectomy surgery in Khalili Hospital

Participants/Inclusion and exclusion criteria
Entry Requirements: People's willingness to participate in the study Range of ages 18 to 70 years Admission for at least 1 day before surgery; Lack of mental illness; No contraindication for using non-steroidal anti-inflammatory drugs and analgesics No drug addiction The patient has the ability to see and hear Patients who are candidates for retinal detachment have a vitrectomy in one eye. The patient should be placed in the group "I" or "II" according to the physical state of the ASA Exit Conditions Study: Failure to speak Non-Iranian nationality Any factor that causes the patient to be unavailable after the operation

Intervention groups
Intervention:Preparation of didactic videos and photographs about the environment of the operative room, type of surgery, presurgery and postsurgery conditions, type of anesthesia, training of pain control without medication, and also oral explanation to the question. study group's patients who receive multimedia training. The control group includes the people who receive routine care.

Main outcome variables
preoperative anxiety and postoperative pain and consumption of analgesic

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180603039968N1**
Registration date: **2018-10-10, 1397/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-10, 1397/07/18**
Update count: **0**

Registration date
2018-10-10, 1397/07/18

Registrant information

Name
Esmaeil Kargar doulat abadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3726 1158

Email address
kargarda@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-10-23, 1397/08/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Patient Preparation by Multimedia Method on Anxiety, Pain, and Consumption of analgesic after Vitrectomy surgery.

Public title

The Effect of Patient Preparation by Multimedia Method on Anxiety, Pain, and Consumption of analgesic after Vitrectomy surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

People's willingness to participate in the study Age range of 18 years old to 70 years old Hospitalization for at least 1 day before surgery No history of mental illness No prohibition of non-steroidal anti-inflammatory drugs and analgesics No addiction to drugs The patient should have the ability of seeing and hearing Patients who are candidates for single-eye vitrectomy surgery because of retinal detachment The patients will be placed in group I or group II according to the physical state of ASA

Exclusion criteria:

Inability to speak Non-Iranian nationality Any factor that leads the patient to become unresponsive after surgery Having the history of attending anxiety control and problem-solving training classes

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **3**

Anxiety, Pain, and Consumption of analgesic

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block Each block represents a week. Each block size is equivalent to 4 days of a week when vitrectomy surgeries are conducted. The days when the vitrectomy surgery is conducted:Sunday, Monday, Tuesday and Thursday In this method, the study group is named as group A and the control group is named as group B. According to the existing conditions, 6 blocks are likely to be as follows: 1-AABB 2- ABAB 3 ABBA 4- BBAA 5- BAAB 6- BABA Selection of blocks is random and based on the cards' shuffling. By selecting each card, the samples are respectively placed in the control or study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

• In order to blindness in the study, researchers and statistical advisers will be unaware of the allocation of patients in the control or intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Street Karim Khan Zand; Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2018-06-02, 1397/03/12

Ethics committee reference number

IR.SUMS.REC.1397.212

Health conditions studied

1

Description of health condition studied

Anxiety; Pain; Retinal detachment;vitrectomy؛ Preoperative preparation; Multimedia education

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

anxiety

Timepoint

The night before the operation and 30 minutes before entering the operating room

Method of measurement

Spielberger questionnaire

2

Description
pain
Timepoint
In the recovery room before entering the department; 1,2,3,4 hours after entering the department
Method of measurement
VAS

3

Description
consumption of analgesics
Timepoint
In the recovery room before entering the department; 1,2,3,4 hours after entering the department
Method of measurement
mg

Secondary outcomes

empty

Intervention groups

1

Description
Study group: After selecting the block, the allocation of patients to the study group is determined. On the night before the surgery, by considering the entry requirements of the study, and after having effective communication and gaining patient's trust, we will start to explain the process to the patient, gain his/her satisfaction and describe the research goals. Patient information is also recorded and the Spielberger questionnaire is filled in. Patients receive routine medical and nursing care according to the hospital policies. Afterward, some didactic photographs and videos will be shown to the patient by using a tablet, and his/her oral questions will be answered. The investigator explains to the patient about non-pharmacological pain control methods as the complementary of pharmacological therapies. In the next step, 30 minutes before entering the operating room, patient's information is recorded and the Spielberger questionnaire is filled in. All patients undergo the general anesthesia. After surgery, at intervals before entering the department, and 1, 2, 3, and 4 hours after entering the department, the level of pain and consumption of pain killers will be measured.
Category
N/A

2

Description
Control group: After selecting the block, the allocation of patients to the control group will be determined. On the night before the operation, by considering the entry requirements of the study, after describing the process and gaining satisfaction of the patient, the patient's information will be recorded and the Spielberger questionnaire will be filled in. the control group's patients will receive routine medical and nursing care according to hospital policies. In the next step, 30 minutes before entering the operating room, patient's information is recorded and the Spielberger questionnaire is filled in. All patients undergo the general anesthesia. After surgery, at intervals before entering the department, and 1, 2, 3, and 4 hours after entering the department, the level of pain and consumption of pain killers will be measured.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalili hospital
Full name of responsible person
Esmaeil Kargar
Street address
Shiraz, Kalili Street
City
Shiraz
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7193616641
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Molazem
Street address
Shiraz, Karim Khan Zand St., Shiraz University of Medical Sciences
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+98 71 3235 7282
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Molazemzah@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Esmaeil Kargar

Position
master student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Shiraz - Khalili Street Khalili Hospital

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
master student

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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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
Mean of anxiety score, mean of pain anxiety score, mean of blood pressure, mean of consumption of analgesic

When the data will become available and for how long
6 months after printing results

To whom data/document is available
All people

Under which criteria data/document could be used
If allowed, Shiraz University of Medical Sciences and authors are allowed to access

From where data/document is obtainable
esmaeil Kargar. Contact number: 00989380676316 esmaeil.kargarda@gmail.com Zahra molazem Associate Professor of Fatemeh Nursing and Midwifery Faculty molazemzah@yahoo.com

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

Contact authors email

Comments