Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparing the effect of GUIDED IMAGERY and CRYOTHERAPY(cold compress) on post operative pain severity and vital signs among laparoscopic cholecystectomy inpatients in Teaching Hospitals

Protocol summary

Study aim
Deviation of attention from classic topics;p generalization and implementation of findings; providing the ground for further research; completing the results of previous studies

Design
The clinical trial has three groups (guided imaging, cryotherapy and control), one-sided blind (the participant has no knowledge of the type and method of code allocation as control and intervention), randomized, sample size of 93 people, 31 people in each group.

Settings and conduct
After obtaining the necessary permits from the Vice-Chancellor of Research and the Ethics Committee, they will be referred to the teaching hospital with an introduction letter in hand, and after checking, confirming and obtaining permission from the authorities. Sampling is done in different shifts and as soon as it is available, and the necessary arrangements will be made beforehand with the personnel of the department for cooperation and information.

Participants/Inclusion and exclusion criteria
Candidate for surgery, consent and desire to participate in the research, have pain with a score of more than 3, no impairment in communication, no cardiovascular disorder...Unwillingness to participate ، occurrence of problems in the continuation of the plan, discharge or death, procedure outside the routine program, use of patient controlled analgesia pump

Intervention groups
Voice or 20-minute images will be used for visualization, including the sounds of the forest, sea, birds, fire and wind. In a calm and quiet environment, the helpers can view the voice or images via hands-free. Patients receive cold therapy in the form of a cold compress in the temperature range of 15-18 degrees Celsius around the laparoscopic site for 20 minutes under the supervision of a specialist consultant.

Main outcome variables
Pain severity; vital signs

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20230723058896N1**
Registration date: **2023-09-09, 1402/06/18**
Registration timing: **prospective**

Last update: **2023-09-09, 1402/06/18**
Update count: **0**

Registration date
2023-09-09, 1402/06/18

Registrant information

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Mahdi Heydari Alinazari

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-11, 1402/06/20

Expected recruitment end date
2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of GUIDED IMAGERY and CRYOTHERAPY(cold compress) on post operative pain severity and vital signs among laparoscopic cholecystectomy inpatients in Teaching Hospitals

Public title

Comparing the effect of GUIDED IMAGERY and CRYOTHERAPY(cold compress) on post operative pain severity and vital signs among laparoscopic cholecystectomy inpatients in Teaching Hospitals

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for laparoscopic cholecystectomy surgery Satisfaction and willingness to participate in the research Age between 20-60 years old Alertness after the operation the disappearance of the effects of anesthetic drugs before the start of the intervention Ability to use numerical scale of pain intensity Having pain with a score greater than 3 No impairment in speech, hearing, vision and communication Ability to speak Persian or Turkish Do not have heart surgery or any cardiovascular disorder Do not have a disease related to the prohibition of the use of cold, such as Raynaud's syndrome No history of nerve diseases (neuropathy, muscle stiffness and poor blood circulation) Any confirmed mental illness

Exclusion criteria:

Unwillingness to participate and continue studying Occurrence of physical problems and inability to continue the plan Discharge of the patient by personal consent or death of the patient Performing any procedure outside the routine schedule Use of PCA pump

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization The current study is a randomized controlled and one-sided blind trial with a sample size of 93 people in the form of three groups, 31 people in the guided imaging group with code one, 31 people in the cryotherapy group with code two, and 31 people in the control group with code three. In order to randomize, in a simple way, numbers from one to three are written on 93 sheets, and applicants who meet the entry criteria are asked to choose one of the numbers from one to three, and by choosing each number, the said number from It goes out between the sheets

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a one blind study with a sample size of 93 people divided into three groups, 31 people in the guided imaging group with code one, 31 people in the cryotherapy group with code two, and 31 people in the control group with code three. In order to randomize, in a simple way, numbers one to three are written on 93 sheets, and applicants who meet the entry criteria are asked to choose one of the sheets , and by choosing each number, the said number is selected from among the sheets. It should be noted that none of the clients have any knowledge about the allocation of codes 1, 2 and 3 to the intervention and control groups and are completely blinded.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of urmia medical university of science

Street address

Research and Technology Vice-Chancellor, Building No. 10, West Azerbaijan University of Medical Sciences and Health Services, Jihad St., Resalat Blvd.

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Approval date

2023-02-01, 1401/11/12

Ethics committee reference number

IR.UMSU.REC.1401.391

Health conditions studied

1

Description of health condition studied

Laparoscopic cholecystectomy

ICD-10 code

K80.01

ICD-10 code description

Calculus of gallbladder with acute cholecystitis with

obstruction

Primary outcomes

1

Description
Pain severity
Timepoint
Before the start of the intervention (zero time) - 15-30-45-60 minutes
Method of measurement
Visual analogue scale questionnaire

2

Description
Vital signs
Timepoint
15-30-45-60 minutes
Method of measurement
Portable monitoring device and thermometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In order to guided imagery , 20-minute voices or images will be used for this purpose under the supervision of a specialist consultant, according to the person's preference, which includes the sounds of the forest, sea, birds, fire and wind. Seekers in a calm and quiet environment. Voices or images. will receive through hands-free and pain intensity through the visual questionnaire of pain intensity (VAS) and vital signs by SAADAT brand portable monitor (calibrated and identical device) and to control the body temperature from the forehead area by infrared digital thermometer made in China The SK-30 INFRARED THERMOMETER model will be used and will be measured in 15-30-45-60 minutes. In addition to the mentioned times, we also measure the starting time (zero) of pain severity
Category
Rehabilitation

2

Description
Intervention group: Patients receive cold therapy in the form of a cold compress in the temperature range of 15-18 degrees Celsius around the laparoscopic site for 20 minutes on a dressing that acts as a barrier to prevent direct contact and non-deep pressure, under the supervision of a specialist consultant, and in minutes 15-30-45-60 pain intensity is measured by (VAS) and vital signs by portable monitor and temperature by digital infrared thermometer. In addition to the mentioned times, we also measure the starting time (zero) of pain severity
Category
Prevention

3

Description
Control group: No intervention will be done in the control group.The intensity of pain in the patient after entering the department is measured 5 times - once immediately after entering the department and then in 15-30-45-60 minutes and vital signs are measured in 15-30-45-60 minutes and the collected data Demographic information will be recorded in the form for review and comparison. It should be noted that the client will receive treatment measures and painkillers if needed and with the order of the attending physician. The type and dose of painkillers received will be recorded in the demographic information form for review and comparison. During the entire study, the researcher will be present with all the patients of all three groups.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeyni teaching hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available