

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of Vibration and Exercise on Shoulder Pain for Patients after Laparoscopic Cholecystectomy : A Randomized Clinical Trial

Protocol summary

Study aim

To determine the effect of the application of vibration and exercise on shoulder pain for patients after laparoscopic cholecystectomy

Design

The true experimental design was employed to achieve the aforementioned objectives. patients will be allocated into two groups study and control (each group with 35 cases) in the study group patients is given exercise and vibration The total sample size would be 70 patients.

Settings and conduct

70 patients with shoulder pain after surgery, were visiting the surgery ward in one major teaching hospital in Baghdad City. Study subjects were recruited when they were seeking the follow-up of their health problems and prescriptions refilling. The simple randomization procedure would involve throwing a dice (eg, below & equal to 3 = control, over 3 = study group). No allocation concealment will be carried out.

Participants/Inclusion and exclusion criteria

Inclusion: *Consent & compliance with all aspects of the study protocol, and methods, and providing data during the follow-up phase. Exclusion: *Medically diagnosed with shoulder pain

Intervention groups

The starting point for the intervention phase will be to ask the patient after two hours from laparoscopic cholecystectomy 'Do you have shoulder pain'. If say yes give a score of pain from 0-10 as a numerical pain scale, this mandatory step will help to identify the severity of patients' pain before and after applying the vibration by a reliable device and stander exercise for the shoulder.

Main outcome variables

Minimizing or relief the shoulder pain after laparoscopic cholecystectomy

General information

Reason for update

Acronym

A Randomized clinical trial (ARCT)

IRCT registration information

IRCT registration number: **IRCT20230310057672N1**

Registration date: **2023-03-30, 1402/01/10**

Registration timing: **prospective**

Last update: **2023-03-30, 1402/01/10**

Update count: **0**

Registration date

2023-03-30, 1402/01/10

Registrant information

Name

Alaa Jawad

Name of organization / entity

University of Baghdad/College of Nursing

Country

Iraq

Phone

+964 1 521 1494

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-02, 1402/01/13

Expected recruitment end date

2023-05-13, 1402/02/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vibration and Exercise on Shoulder Pain for

Patients after Laparoscopic Cholecystectomy : A
Randomized Clinical Trial

Public title

Vibration and Exercise Maneuvers to Minimize Patients' shoulder pain post lap chole: A Randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Consent & compliance with all aspects of the clinical trial, methods, providing data during follow-up phase
Contact male & female patients, who are 18-70 years old at the time of the data collection phase

Exclusion criteria:

Involvement with any other ongoing studies. Medically diagnosed with psycho-mental diseases. Patients who suffer from shoulder pain before undergoing laparoscopic cholecystectomy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to maintain a transparent & scientific-based randomization process, simple randomization will be used in assigning participants (patients with shoulder pain), to intervention & control groups, assuming that each participant has an equal chance of being assigned to any group. The simple randomization procedure would involve throwing the dice (eg, below & equal to 3 = control, over 3 = intervention). No allocation concealment will be carried out.

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

Research Ethical Approval Committee, at the College of Nursing

Street address

Bab AL-Muadum

City

Baghdad

Postal code

10001

Approval date

2022-12-07, 1401/09/16

Ethics committee reference number

4499

Health conditions studied

1

Description of health condition studied

Pain in Shoulder after laparoscopic cholecystectomy

ICD-10 code

M25.519

ICD-10 code description

Pain in unspecified shoulder

Primary outcomes

1

Description

Shoulder Pain after Laparoscopic Cholecystectomy (Relief or Minimize)

Timepoint

The clinical intervention of the experiment is carried out two hours after the laparoscopic gallbladder removal operation for patients, and the results of the intervention appear to reduce the intensity of shoulder pain from the first postoperative day to the third day.

Method of measurement

Measurement method before and after clinical intervention using a numerical pain scale to measure shoulder pain

Secondary outcomes

1

Description

Minimize Patients' shoulder pain post lap chole

Timepoint

The secondary outcome is measured following the application of intervention and after 2-4 hours on the same day of intervention

Method of measurement

Interview Method: The patient has shoulder pain after laparoscopic cholecystectomy

Intervention groups

1

Description

Intervention group: The starting point for the intervention phase will be to ask the patient after two

hours from laparoscopic cholecystectomy 'Do you have shoulder pain' questionnaire. If say yes give a score of pain from 0-10 as a numerical pain scale, this mandatory step will help to identify the severity of patients' pain before and after applying the vibration by a reliable device and stander exercise for the shoulder (Williams & Wilkins, 2011). We will evaluate the effectiveness of the clinical intervention on the same first day after laparoscopic cholecystectomy to the third day.

Category

Other

2**Description**

Control group: In order to be matched with patients in the intervention group, control group subjects with shoulder pain after laparoscopic cholecystectomy will be determined. No intervention will be given to them during the study.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Surgical ward in AL-Kindi Teaching Hospital and Baghdad Teaching Hospital

Full name of responsible person

Alaa Jawad Kadhim, Noorah Mahmoud Ali

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<https://www.medicalcity.gov.iq/ar/contact-us>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

College of Nursing, University of Baghdad

Full name of responsible person

Professor Huda Baker Hassan, PhD. Dean

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

The author of the trial is the funding source

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**

University of Baghdad, College of Nursing

Full name of responsible person

Alaa Jawad Kadhim

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Web page address

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

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

The researcher is acknowledging the scientific community to have verifiable findings of the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals.

When the data will become available and for how long

God willing, once finishing the process of data collection, analysis, and successful publishing of the manuscript, all the related files will become available for Five months after the publications

To whom data/document is available

All the related files will be shared with any scientific interested parties.

Under which criteria data/document could be used

It may be used after seeking the author's permission and acknowledging his contribution

From where data/document is obtainable

The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail: alaaj@conursing.uobaghdad.edu.iq

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

N/A

Comments

Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors.