

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of massage therapy and Transcutaneous Electric Nerve Stimulation (TENS) on shoulder pain in patients after laparoscopic cholecystectomy

Protocol summary

Study aim

Determining and comparing the effect of massage therapy and Transcutaneous electrical nerve stimulation (TENS) on shoulder pain in patients after laparoscopic cholecystectomy

Design

Clinical trial on 180 patients who were candidates for laparoscopic cholecystectomy with a control group, based on the target population, double-blind and randomized by block method with a volume of 6

Settings and conduct

This study is performed on patients who are candidates for laparoscopic cholecystectomy in Imam Reza (AS) Hospital in Kermanshah. Massage and TENS techniques are performed after cholecystectomy (4, 8 and 12 hours after Surgery) in three steps. pain intensity 20 minutes before and after each intervention period are assessed using the Visual Analogue Scale (VAS)

Participants/Inclusion and exclusion criteria

Inclusion criteria: VAS shoulder pain intensity score at baseline (within 3 hours after surgery) According to the American Society of Anesthesiology (ASA) classification, the patient is in grade 1 or 2 Satisfaction to participate in research orally and in writing Exclusion criteria: Having wounds, phlebitis, trauma arthritis in the massage area Having a cognitive psychomotor disorder Opioid addiction Having shoulder pain before surgery

Intervention groups

Examples include three groups: massage therapy, Transcutaneous electrical nerve stimulation (TENS), and control. The control group will include patients who have not had an intervention and will receive routine care. The massage therapy group massages the hand area for 30 minutes. In the TENS method, the electrodes are placed near or on the pain site and send the stimuli created by the device to the skin to stimulate the sensory-nerve terminals.

Main outcome variables

Patients's shoulder pain score based on the VAS scale

General information

Reason for update

By updating the study, we try to complete the research process, and for this reason, we made the necessary corrections to achieve more explicit results.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200206046395N1**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **prospective**

Last update: **2022-03-19, 1400/12/28**

Update count: **1**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

Mobin Mottahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3233 8090

Email address

mobinmottahedi1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of massage therapy and Transcutaneous Electric Nerve Stimulation (TENS) on shoulder pain in patients after laparoscopic cholecystectomy

Public title

Comparison of the effect of massage therapy and Transcutaneous Electric Nerve Stimulation (TENS) on shoulder pain in patients after laparoscopic cholecystectomy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

A VAS Shoulder pain intensity score at baseline (within 3 hours after surgery) of greater than or equal to 30 mm on a 100 mm VAS scale with 0 = no pain and 100 = worst pain imaginable. According to the American Society of Anesthesiology (ASA) classification, the patient is in grade I or II consent to participate in oral and written research Not to have internal cardiac pacemaker Not pregnancy

Exclusion criteria:

having wounds, phlebitis, trauma arthritis in the massage area Having a cognitive psychomotor disorder Addiction to painkillers and opiates Cardiovascular disease Having shoulder pain before surgery

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **180****Randomization (investigator's opinion)**

Randomized

Randomization description

Pre-sampling of the type will be available. Then, the samples studied in this study will be placed in the study groups (control, TENS intervention and massage intervention) using random allocation of patients. The random allocation sequence is determined using the block method with a volume of 6 using the software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is double-blind because participants receiving the intervention are aware of the intervention.

The data collector will not be aware of the patient group.

The data analyzer will not be aware of the patient group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Building No. 2 of Kermanshah University of Medical Sciences, Shahid beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2022-01-11, 1400/10/21

Ethics committee reference number

IR.KUMS.REC.1400.757

Health conditions studied**1****Description of health condition studied**

Laparoscopic cholecystectomy

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

Primary outcomes**1****Description**

Shoulder pain score in Visual Pain Scale Questionnaire

Timepoint

Before intervention, baseline (within 3 hours after surgery). 4, 8 and 12 hours after surgery

Method of measurement

VAS Visual Analog Scale

Secondary outcomes

1

Description

Taking analgesic drugs

Timepoint

end of surgery

Method of measurement

check list

2

Description

Time of the first dose of analgesic

Timepoint

end of surgery

Method of measurement

check list

Intervention groups

1

Description

Intervention group: Massage - Massage therapy group 30 minutes with three massage methods Petrisag-Kneading-Friction in the hand area. This technique is performed three times after cholecystectomy (4, 8 and 12 hours after surgery). Patients' pain intensity is measured and recorded 20 minutes before and after each massage with the Visual Pain Scale (VAS).

Category

Treatment - Devices

2

Description

Intervention group: TENS In the TENS method, electrodes are placed near or on the shoulder pain site and send the stimuli created by the device to the skin to stimulate the sensory-nerve terminals. Also, in order to achieve effective and rapid pain relief, the TENS current (frequency of 150 Hz and a pulse width of 75 μ s) Used for 30 minutes. the intensity of each channel was increased until the participant was able to feel a maximal tolerable tingling sensation without causing discomfort, pain, or muscle contraction. This technique is performed three times after cholecystectomy (4, 8 and 12 hours after surgery). Patients' pain intensity is measured and recorded 20 minutes before and after each TENS with a Visual Analogue Scale (VAS).

Category

Treatment - Devices

3

Description

Control group: Get routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Kermanshah

Full name of responsible person

MOBIN MOTTAHEDI

Street address

Kermanshah-Nurse Boulevard

City

kermanshah

Province

Kermanshah

Postal code

6718743161

Phone

+98 83 3427 6300

Email

info@irhk.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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Province

Kermanshah

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6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

MOBIN MOTTAHEDI

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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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

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

Title and more details about the data/document

Individual participant data collected for the primary outcome measures

When the data will become available and for how long

After publication for one year

To whom data/document is available

For all people who request for data

Under which criteria data/document could be used

It is allowed to perform any analysis on the data, but use of data for publication is not allowed.

From where data/document is obtainable

Corresponding author of article

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

After requesting the data by email to corresponding author, the data will be sent after a maximum period of one week

Comments