

# 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

**Age**From **18 years** old to **60 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser

**Sample size**Target 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  $\mu$ 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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

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**

Operating room

**Street address**

Square of kargar\_navvab

**City**

shahrood

**Province**

Semnan

**Postal code**

3618675313

**Phone**

009832338090

**Email**

Mobinmottahedi1372@gmail.com

## Person responsible for scientific 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**

operating room

**Street address**

Square kargar-navvab

**City**

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**Province**

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3618675313

**Phone**

009832338090

**Email**

mobinmottahedi1372@gmail.com

## Person responsible for updating data

### 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**

operating room

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**City**

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3618675313

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009832338090

**Email**

mobinmottahedi1372@gmail.com

## 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**