

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Local Heat Therapy on Shoulder Pain of after Laparoscopic Cholecystectomy

Protocol summary

Study aim

The effect of topical heat therapy on shoulder pain after laparoscopic gallbladder surgery

Design

clinical trial that randomized clinical trial method is throwing the dice. Non-blind, with three groups (right shoulder heat therapy and heat treatment operation and control), with parallel groups with sample size of 61

Settings and conduct

This study was a randomized clinical trial and patients were assigned to three groups of right shoulder warmth, positional heat therapy and control based on simple randomization. The sample size was 20 persons in each group and the study site was Allameh Behlul Hospital of Gonabad. There was no intervention for control group patients. For right shoulder and position shoulder surgery group, the patients were treated for 20 minutes after expressing pain.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 to 60 years, laparoscopic cholecystectomy, patient's willingness to participate in the study Exclusion criteria include: history of shoulder surgery and anatomical abnormalities, shoulder dislocation or fracture, underlying disease such as diabetes and peripheral vascular disease, drug addiction, acute cholecystitis, common bile duct stones, recent pancreatitis and jaundice , Gallbladder rupture and bile leak at the site of operation and severe intraoperative bleeding

Intervention groups

Intervention group 1: Silicate hot pack heated by Hot Pack at 70 ° C, wrapped around towel at 50 ° C for 20 minutes in right shoulder, Pain severity was measured after the intervention at 20 and 40 minutes by visual analogue scale. Intervention group 2: All of the above steps were performed except the hot water bag was in the operative position. Control group: In this group all of these procedures except the hot water bag were performed.

Main outcome variables

Shoulder pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180221038821N3**

Registration date: **2019-12-13, 1398/09/22**

Registration timing: **retrospective**

Last update: **2020-03-25, 1399/01/06**

Update count: **1**

Registration date

2019-12-13, 1398/09/22

Registrant information

Name

Iman Ghorbany Moghaddam

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-02-04, 1397/11/15

Actual recruitment end date

2019-09-12, 1398/06/21

Trial completion date

2019-09-23, 1398/07/01

Scientific title

Effect of Local Heat Therapy on Shoulder Pain of after Laparoscopic Cholecystectomy

Public title

Effect of Local Heat Therapy on Shoulder Pain of after Laparoscopic Cholecystectomy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 18 to 60 years Surgery by laparoscopic cholecystectomy Patient willingness to participate in the study

Exclusion criteria:

Shoulder surgery history and anatomical abnormalities and shoulder dislocation or fractures Underlying disease such as diabetes and peripheral vascular disease Drug addiction Acute cholecystitis Common bile duct stones Recent pancreatitis and jaundice Gallbladder rupture and bile leak at the site of operation Severe intraoperative bleeding

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were selected using purposive sampling method and applying inclusion criteria. Then by throwing dice, three right shoulder thermotherapy group (numbers 1 and 2), Therapeutic stance of action (numbers 3 and 4) and control (numbers 5 and 6) were assigned.

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**

Ethical Committee of Gonabad University of Medical Sciences

Street address

Asian Road Rim, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

96916-47161

Approval date

2018-11-22, 1397/09/01

Ethics committee reference number

IR.GMU.REC.1397.091

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

cholecystectomy

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

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

Severity of shoulder pain after laparoscopic cholecystectomy

Timepoint

Before intervention, 20 and 40 minutes after intervention

Method of measurement

Pain severity was measured using the Visual Analogue Scale.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: In this group, thermotherapy for research units were placed in the right shoulder by using a hot water bag heated to 70 ° C, wrapped around a towel and 50 ° C, for 20 minutes.

Category

Other

2**Description**

Intervention group2: In this group, thermotherapy for research units were Position surgery by using a hot water

bag heated to 70 ° C, wrapped around a towel and 50 ° C, for 20 minutes.

Category

Other

3

Description

Control group: For the research units in this group only routine care was performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlol Hospital, Gonabadi

Full name of responsible person

Dr. Abbas Ebadi

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Parastar Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Fatemeh Ansari

Position

MSc of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Razavi Khorasan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPDAfter receiving the results of the decision for the
publication, I will produce results.**Study Protocol**

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available