Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Local Heat Therapy on Shoulder Pain of after Laparascopic 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
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Name of organization / entity
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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 Laparascopic Cholecystectomy

Public title
Effect of Local Heat Therapy on Shoulder Pain of after Laparascopic 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Position
MSc of Nursing

Latest degree
Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
After 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