

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Assessment the effect of incentive spirometry on intensity of shoulder pain after laparoscopic Cholecystectomy surgery in Mashhad medical sciences University Hospitals In the year 2018

Protocol summary

Study aim

The effect of incentive spirometry on intensity of shoulder pain after laparoscopic Cholecystectomy surgery.

Design

Clinical trial with intervention and control group, community based and pragmatic,one blinded, randomized with permutation blocks

Settings and conduct

Research in hospitals affiliated to Mashhad University of Medical Sciences and individuals are sampled according to criteria. Motivating spirometry training Before surgery and after surgery and consciousness, the patient is asked to take 10 breaths (inside the tube and exhalation in the open air) every 2 hours to 12 hours. The shoulder pain should be measured at 4.8, 12.24, and 48 hours later.

Participants/Inclusion and exclusion criteria

Age between 18 and 65.full satisfaction,cholecystitis diagnosis,full consciousness, located under General anesthesia and having pain in one or both shoulders:having mental illness and anxiety disorders, having Underlying diseases such as respiratory diseases,history of addiction to any substance drugs and cigarettes,history of diabetes and neuropathy ,pregnancy,there is any shoulders disorder

Intervention groups

The control group receives the medication according to the prescribing physician. The intervention group receives a motile spirometry.

Main outcome variables

Effect of on shoulder pain after laparoscopic cholecystectomy with non-pharmacological and low-cost technique; Effect on surgical pulmonary complications and improvement of respiratory function in patients undergoing laparoscopic cholecystectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181106041569N1**

Registration date: **2018-11-24, 1397/09/03**

Registration timing: **prospective**

Last update: **2018-11-24, 1397/09/03**

Update count: **0**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

Mehri sadat Saremi rad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 1416

Email address

smirad1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-03-30, 1398/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of incentive spirometry on intensity of shoulder pain after laparoscopic Cholecystectomy surgery in Mashhad medical sciences University Hospitals In the year 2018

Public title

The Effect of Motivational Spirometry on Shoulder Pain After Laparoscopic Laparoscopic Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years Have complete satisfaction to participate in research Have at least reading and writing skills Diagnosis of cholecystitis based on sonography and general surgeon's opinion Complete vigilance Patients undergoing laparoscopic cholecystectomy Subjects under general anesthesia (for all patients with anesthetic drugs) miazolam and atracurium ampoules for total muscle relaxation as a pre-operative drug Ampoules Nesodnal is used as an anesthetic for patients during surgery, then co2 gas is injected to 8 mm Hg pressure in the patient's abdomen Having pain in one or both shoulders

Exclusion criteria:

Having known psychological illnesses and anxiety disorders Previous history of laparoscopic surgery Having underlying illnesses like COPD and respiratory diseases A history of addiction to any drug or cigarette History of the use of motivational spirometry A history of diabetes and neuropathy Pregnancy There is any disorder in the shoulders Emergency patient conditions for laparoscopic cholecystectomy Surgical history Duration of surgery for more than 2 hours Injection of drugs out of the prescribed anesthetic protocol Patients who need to have NGT after surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Optionally available and randomly block permutations

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome evaluators are blind in this study, since they do not have any information about the intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Shahrak Tohid Blvd, Block 1, Sabzevar University Of Medical Sciences

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Postal code

9613873137

Approval date

2018-11-04, 1397/08/13

Ethics committee reference number

IR.MEDSAB.REC.1397.055

Health conditions studied

1

Description of health condition studied

Shoulder pain after laparoscopic Cholecystectomy surgery

ICD-10 code

Z90.4

ICD-10 code description

Acquired absence of other specified parts of digestive tract

Primary outcomes

1

Description

The percentage of patients undergoing laparoscopic cholecystectomy after shoulder pain

Timepoint

Severe shoulder pain after 4.8.12,24 and 48 hours to be measured

Method of measurement

Pain measurement tool (questionnaire)

Secondary outcomes

1

Description

Incentive spirometry

Timepoint

From 2 hours after surgery of both the morning and afternoon shifts at two hours (12 hours)

Method of measurement

Observation

Intervention groups

1

Description

Control group: Receives analgesic drugs according to the protocol. Patients receive Non_steroidal Anti inflammatory Drug after surgery.

Category

Prevention

2

Description

Intervention group: receptor spirometry. The patient is given necessary training before surgery and after 2 hours of surgery and alertness the patient is asked to do it for up to 12 hours every two hours. The patient's pain is measured at 4.8.12.24 and 48 hours later with a pain measuring instrument. For each patient, one Oral tube is used separately.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza and Omid Hospitals

Full name of responsible person

Mehri Sadat Saremi Rad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Doctor Fereshteh Ghorat

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Mehri Sadat Saremi Rad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Hamideh Yazdi

Position

PhD in Nursing

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Other areas of specialty/work

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

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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

Sabzevar University of Medical Sciences

Full name of responsible person

Mehri Sadat Saremi Rad

Position

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