

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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 shoulder 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

##### City

Sabzevar

##### Province

Razavi Khorasan

##### 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

**Street address**

Kohsangi Blvd.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3726 9021

**Email**

emamreza@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Doctor Fereshteh Ghorat

**Street address**

Shahrak Tohid Blvd, Block 1, Sabzevar University of

Medical Sciences

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613873137

**Phone**

+98 51 4401 1060

**Email**

ghoratif@medsab.ac.ir

**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

**Street address**

No.24, Modares 20 Ave.

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617753544

**Phone**

+98 51 4422 1416

**Email**

saremi95@medsab.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Hamideh Yazdi

**Position**

PhD in Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Shahrak Tohid Blvd, University of Medical Science

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613873137

**Phone**

+98 51 4401 1000

**Email**

yazdih@medsab.ac.ir

**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**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No.24 , Modares 20 Ave

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617753544

**Phone**

+98 51 4422 1416

**Email**

saremi95@medsab.ac.ir

**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