

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### Comparing the effect of the application of pulmonary recruitment maneuver and supplemental oxygen therapy and their combination on shoulder pain and nausea and vomiting in patients undergoing laparoscopic cholecystectomy in the Shahid Arefian Hospital of Urmia

#### Protocol summary

##### Study aim

The effect of pulmonary recruitment maneuver and supplemental oxygen therapy and their combination on shoulder pain, nausea, and vomiting in patients undergoing laparoscopic cholecystectomy

##### Design

100 patients will be randomly divided into four groups A, B, C, D, with a ratio of 1:1:1:1. The main researcher (anesthesiologist) has been working for 10 years and has complete mastery of both of these methods; This technique will be performed under the supervision of an anesthesiologist and a surgeon.

##### Settings and conduct

In the operating room of Arefian Hospital in Urmia, shoulder pain will be assessed using VAS tools in 4, 12, and 24 hours after surgery in all groups. Rhodes-induced nausea and vomiting will be assessed in 12 and 24 hours after surgery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with anesthesia class one and two in the age range of 35 to 55 years and no underlying diseases and nausea and vomiting, non-smoking /  
Exclusion conditions: Patients with intra-abdominal pressure more than 14 mm Hg, receiving anti-inflammatory drugs Vomiting, infectious infection of the peritoneal cavity, and adhesions, change of surgical procedure to laparotomy, underlying disease, smoking

##### Intervention groups

combined method group (A), two interventions of pulmonary recruiting maneuvers with complementary oxygen therapy will be performed. In the pulmonary recruiting group (B), the ventilator airway pressure relief valve will close to fill the bag. Then five manual breaths will be given. For supplemental oxygen therapy group (C), the moment the patient enters the ward until 6 hours later, oxygen will be administered through the

nasal cannula 4 lit/min. In the control group (D), the usual procedure will be performed by applying gentle abdominal pressure to remove CO2 through the port site at the end of surgery.

##### Main outcome variables

Shoulder pain and nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211013052762N1**

Registration date: **2021-11-18, 1400/08/27**

Registration timing: **prospective**

Last update: **2021-11-18, 1400/08/27**

Update count: **0**

##### Registration date

2021-11-18, 1400/08/27

##### Registrant information

##### Name

hamed tayyeb

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3276 2050

##### Email address

hamed7197@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-01, 1400/09/10  
**Expected recruitment end date**  
 2022-01-20, 1400/10/30  
**Actual recruitment start date**  
 empty  
**Actual recruitment end date**  
 empty  
**Trial completion date**  
 empty

**Scientific title**  
 Comparing the effect of the application of pulmonary recruitment maneuver and supplemental oxygen therapy and their combination on shoulder pain and nausea and vomiting in patients undergoing laparoscopic cholecystectomy in the Shahid Arefian Hospital of Urmia

**Public title**  
 comparing the effect of the application of pulmonary recruitment maneuver and supplemental oxygen therapy and their combination on shoulder pain and nausea and vomiting in patients undergoing laparoscopic cholecystectomy in the Shahid Arefian Hospital of Urmia city in 2021

**Purpose**  
 Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients with anesthesia class one and two and can communicate verbally Patients in the age range of 35 to 55 years Candidate for elective laparoscopic cholecystectomy with general anesthesia No chronic obstructive pulmonary, renal, hepatic, cardiac, gastrointestinal and cerebral diseases No history of diseases causing nausea and vomiting No electrolyte disturbance No motion sickness No smoking  
**Exclusion criteria:**  
 Patients whose intra-abdominal pressure is more than 14 mm Hg during surgery. No concomitant non-laparoscopic surgery Receive antiemetic drugs before and after surgery Peritoneal cavity infection Hemoperitoneum and multiple adhesions in the peritoneum and peripheral when surgical procedure changed to laparotomy. Having a history of laparotomy Having any underlying disease Smoking

**Age**  
 From **35 years** old to **55 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
 Target sample size: **100**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**

In this study, random allocation with a ratio of 1: 1: 1: 1 will be divided into four groups: pulmonary record, complementary oxygen therapy, combined method (pulmonary record and complementary oxygen therapy), and control using the secure envelope method. In this way, inside the envelopes, closed sheets will contain all four approaches with equal proportions and sample volumes. Before starting the interventions, a person not related to the research will randomly select one of the sheets. Moreover, the patient will subsequently be assigned to that group. Due to the nature of the study, the patient will not know which group will be assigned. Also, when analyzing the data, the groups will be provided to the statistical analyst anonymously with the English letters A, B, C, and D; Therefore, the study will be double-blind.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

The present study will be a double-blind, four-group, 2 \* 2 factorial design clinical trial.

#### **Placebo**

Not used

#### **Assignment**

Factorial

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Urmia university of medical sciences

##### **Street address**

Resalat Boulevard, Emergency Alley

##### **City**

Urmia

##### **Province**

West Azarbaijan

##### **Postal code**

5714783734

#### **Approval date**

2021-09-29, 1400/07/07

#### **Ethics committee reference number**

IR.UMSU.REC.1400.249

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

Cholelithiasis

#### **ICD-10 code**

K80.0

#### **ICD-10 code description**

Calculus of gallbladder with acute cholecystitis

## Primary outcomes

### 1

#### Description

Shoulder pain

#### Timepoint

In recovery, 6, 12 and 24 hours after surgery

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Nausea and Vomiting

#### Timepoint

12 and 24 hours after surgery

#### Method of measurement

Rhodes scale

## Intervention groups

### 1

#### Description

The first intervention group: in the combined method group (group A), a combination of two interventions of pulmonary recruitment maneuver combined with complementary oxygen therapy.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: In pulmonary recruiting group (group B), the air pressure relief valve will be closed on the ventilator to fill the bag. Then five manual breaths will be given for each breath for 5 seconds.

#### Category

Treatment - Other

### 3

#### Description

Intervention group: Intervention group 3: For the supplemental oxygen therapy group (group C), routine surgical interventions will be performed and from the moment the patient enters the ward until 6 hours later, 2 to 4 liters of oxygen per minute will be prescribed for the patient.

#### Category

Treatment - Other

### 4

#### Description

Control group: In the control group (group D), the usual procedure will be performed by applying gentle abdominal pressure to remove CO<sub>2</sub> through the port at

the end of surgery.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Arefian Hospital

##### Full name of responsible person

Yaser moradi

##### Street address

Resalat Boulevard, Emergency Alley

##### City

Urmia

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##### Postal code

5714783734

##### Phone

+98 44 3223 4897

##### Email

yasermoradi1045@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Iraj Mohebi

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research@umsu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Oroumia 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

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Oroumia University of Medical Sciences  
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Assistant Professor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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