

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the effect of arterial carbon dioxide pressure and nausea, vomiting and pain after laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

Comparison of the effect of arterial carbon dioxide pressure and nausea, vomiting and pain after laparoscopic cholecystectomy

##### Design

The study will be double blind and clinical trial. Sixty patients will be randomly divided into 2 groups. The groups are parallel.

##### Settings and conduct

Patients undergo laparoscopic cholecystectomy in Valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 years old; ASA class one and two; candidate for laparoscopic cholecystectomy surgery; no chronic use of narcotic drugs, NSAIDs, and benzodiazepines. Exclusion criteria: change of laparoscopic surgery to open surgery; prolongation of the operation time more than 3 hours; need for blood transfusion during the operation; lack of consent to continue participating in the study.

##### Intervention groups

The first intervention group: in one group, patients will receive standard CO<sub>2</sub> gas pressure (14-15 mmHg) during surgery. The second intervention group: In the second group, they will receive low pressure CO<sub>2</sub> gas (7-9 mm Hg).

##### Main outcome variables

HCO<sub>3</sub>; PH; PCO<sub>2</sub>; incidence and severity of nausea and frequency and vomiting score and pain intensity at the operation site; amount of ondansetron and dose of pethidine used; shoulder pain

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20141209020258N185**

Registration date: **2023-05-30, 1402/03/09**

Registration timing: **prospective**

Last update: **2023-05-30, 1402/03/09**

Update count: **0**

#### Registration date

2023-05-30, 1402/03/09

#### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-06-06, 1402/03/16

#### Expected recruitment end date

2023-06-06, 1402/03/16

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of arterial carbon dioxide pressure and nausea, vomiting and pain after laparoscopic cholecystectomy

## Public title

Comparison of the effect of arterial carbon dioxide pressure and nausea, vomiting and pain after laparoscopic cholecystectomy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age: 18 to 65 years old ASA class I and II Candidate for laparoscopic cholecystectomy surgery No chronic use of narcotics, NSAIDs and benzodiazepines

### Exclusion criteria:

Changing laparoscopic surgery to open surgery  
Extending the operation time more than 3 hours  
The need for blood transfusion during the operation  
Dissatisfaction to continue attending the study

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Due to the double-blindness of the study, the patients and the data collector (intern) do not know about the groupings, but the anesthesiologist who is on the patient's bed during surgery knows about the groupings.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

Ethics committee

## Name of ethics committee

Ethics Committee Arak University Of Medical Sciences

## Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

## City

Arak

## Province

Markazi

## Postal code

848176941

## Approval date

2023-04-16, 1402/01/27

## Ethics committee reference number

IR.ARAKMU.REC.1402.014

## Health conditions studied

### 1

#### Description of health condition studied

Laparoscopic cholecystectomy

#### ICD-10 code

K91.86

#### ICD-10 code description

Retained cholelithiasis following cholecystectomy

## Primary outcomes

### 1

#### Description

Arterial blood gas

#### Timepoint

The beginning of the action and the end of the action

#### Method of measurement

Blood test

### 2

#### Description

Nausea

#### Timepoint

From the time of entering recovery and every 15 minutes to one hour and 2, 4, 8, 12 and 24 hours after surgery.

#### Method of measurement

Physical examination

### 3

#### Description

vomitting

#### Timepoint

From the time of entering recovery and every 15 minutes to one hour and 2, 4, 8, 12 and 24 hours after surgery.

#### Method of measurement

Physical examination

### 4

#### Description

Pain

## Timepoint

Recovery and 4 hours after surgery

## Method of measurement

Visual analog scale of pain

## 5

### Description

Mean Ondansetron

### Timepoint

At the end of the study

### Method of measurement

Physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group: in one group, patients will receive standard CO<sub>2</sub> gas pressure (14-15 mmHg) during surgery.

#### Category

Treatment - Surgery

### 2

#### Description

The second intervention group: In the second group, they will receive low pressure CO<sub>2</sub> gas (7-9 mm Hg).

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr hospital

##### Full name of responsible person

Dr Behnam Mahmodie

##### Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Email

mahmodie@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mehdi Salehi

##### Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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##### Fax

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##### Email

salehi@arakmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Dr Hesamedin Modir

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

##### City

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##### Province

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##### Postal code

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##### Phone

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**Email**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Behnam Mahmodie

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Maedeh Ebrahimi

**Position**

medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Email**

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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