

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Study on effect of carbon dioxide temperature on prognosis of laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

Study on pain decrease in Patients underlying Laparoscopic Cholecystectomy

##### Design

Study have 2groups of Control and Trial, 48patients are going to be studied. Block Randomization is used and ordered with Statistical Softwares. Study is one-side blinded.

##### Settings and conduct

Patients with diagnosis Cholecystitis hospitalized in Ayatollah Mousavi Hospital, zanzan. will be divided in two Groups. Carbon dioxide used in Laparoscopic Cholecystectomy would have temperature differences. Data of pain is collected with VAS scale. Study in one-side blinded.

##### Participants/Inclusion and exclusion criteria

Include: Patients with diagnosis of Cholecystitis candidate for Laparoscopic Cholecystectomy Exclude: Addiction. Psychologic diseases

##### Intervention groups

Patients with a diagnosis of cholecystitis who are candidates for laparoscopic cholecystectomy are included in the study. Laparoscopic surgery will be performed in two groups with carbon dioxide gas at different temperatures (room temperature and 37 ° C).

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210201050196N1**

Registration date: **2021-02-23, 1399/12/05**

Registration timing: **retrospective**

Last update: **2021-02-23, 1399/12/05**

Update count: **0**

##### Registration date

2021-02-23, 1399/12/05

##### Registrant information

###### Name

naser keikhali

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 24 3345 6006

###### Email address

nkeikhali@zuma.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-20, 1399/09/30

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study on effect of carbon dioxide temperature on prognosis of laparoscopic cholecystectomy

##### Public title

Carbon dioxide in Laparoscopic Cholecystectomy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients with diagnosis of cholecystectomy candidate for cholecystectomy

**Exclusion criteria:**

Exposure to unpredictable consequences unrelated to the surgical technique during surgery  
Need to convert laparoscopic surgery to laparotomy surgery  
Notice significant adhesion around the gallbladder before surgery

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A randomized block is used to randomize the patients under study and to fully observe the randomness of placement in the control group and the sample group, because the inclusion process requires randomization due to the ongoing recruitment. Based on the calculated sample size, the sample size in each group is 24 people for easier application of random blocks to randomize the members of each group. Permutations are considered as 6 permutations according to 2 groups: AABB, ABAB, BBAA, BABA, BAAB, ABBA. The permutations are written on 6 cards and the selection of permutations and their order will be randomly selected from among the cards. The order of exit of the cards is written and will determine the order of recruitment of intervention groups based on it. An individual randomization unit will be used for the study. The information of the registered persons will be anonymous and without their personal information.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is based on one-side blinded methods. Meaning Patients would not be aware of their groups. Only Surgeon knows patients belong to which groups. in addition, the student who collects the data is not aware of patients and their groups too.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Science

**Street address**

Ayatollah Mousavi Hospital, Zanjan

**City**

زنجان

**Province**

Zanjan

**Postal code**

4513956183

**Approval date**

2021-01-05, 1399/10/16

**Ethics committee reference number**

IR.ZUMS.REC.1399.358

**Health conditions studied****1****Description of health condition studied**

Laparoscopic Cholecystectomy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Post surgery pain of patients undergoing Laparoscopic Cholecystectomy

**Timepoint**

Post surgery pain in patients would studied in 6,12,24 hours after surgery.

**Method of measurement**

Based on VAS scale, data would be collected.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: Carbon dioxide used in laparoscopy with room temperature

**Category**

Diagnosis

**2****Description**

Intervention group: Carbon dioxide used in laparoscopy with T= 34-38'c

**Category**

Diagnosis

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Ayatollah Mousavi Hospital

**Full name of responsible person**

Naser keikhali

**Street address**

Ayatollah Mousavi Hospital, zanja

**City**

zanjan

**Province**

Zanja

**Postal code**

4513956183

**Phone**

+98 24 3313 0000

**Email**

Mousavihospital@zums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Zanja University of Medical Sciences

**Full name of responsible person**

Naser Keikhali

**Street address**

Ayatollah Mousavi Hospital

**City**

Zanja

**Province**

Zanja

**Postal code**

4513956183

**Phone**

+98 24 3313 0000

**Email**

Mousavihospital@zums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Zanja 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**

Zanja University of Medical Sciences

**Full name of responsible person**

Naser Keikhali

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

**Street address**

Ayatollah Mousavi Hospital

**City**

Zanja

**Province**

Zanja

**Postal code**

۴۵۱۳۹۵۶۱۸۳

**Phone**

+98 24 3313 0000

**Email**

nkeikhali@zums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zanja University of Medical Sciences

**Full name of responsible person**

Naser Keikhali

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

**Street address**

Mousavi Hospital

**City**

Zanja

**Province**

Zanja

**Postal code**

۴۵۱۳۹۵۶۱۸۳

**Phone**

+98 24 3345 6006

**Fax**

**Email**

nkeikhali@zuma.ac.ir

## Person responsible for updating data

### Contact

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Zanja University of Medical Sciences

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**Fax**

**Email**

nkeikhali@zuma.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