Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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, zanjan. 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)
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+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, zanjan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Naser Keikhali
Position
Associate professor
Latest degree
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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