Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Assessing effect of flow rate of CO2 gas on postoperative complications in laparoscopic surgery

Protocol summary

Study aim
Determination the effect of CO2 gas flow rate on postoperative complications in laparoscopic surgery

Design
This study will be conducted as a randomized, double-blind clinical trial.

Settings and conduct
This study is about the effect of flow rate of CO2 gas on postoperative complications in laparoscopic surgery in Imam Khomeini Hospital in Kermanshah. In this study, the patients and the peoples who measuring the variables would be unaware of the presence of patients in the first group and or in the second groups. Only the surgeon aware about grouping.

Participants/Inclusion and exclusion criteria
Ages between 18 and 65 years old and have laparoscopic surgery; patients with history of motion sickness, diabetes, cardiovascular failure, severe nausea and vomiting in past surgery; patients with concurrent surgery; patients under treatment with narcotic drugs or non-steroidal anti-inflammatory drugs.

Intervention groups
Intervention: In order to be able to do surgery in the abdomen, in new surgery, they injected some CO2 into the abdominal area, until with the opening of the organs from one another, access is easy for surgeon. Speed of entering the gas into the abdominal cavity at the beginning of the laparoscopic surgery is done in both low speed and high speed. Intervention group: patients who are eligible for inclusion in the study are included in the study and without knowing that it is only the first group (under the operation with blowing CO2 gas at low speed) or the second group (under the operation with blowing CO2 gas at high speed) , surgery happens to them.

Main outcome variables
The amount of pain after laparoscopic surgery; nausea; vomitting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100609004141N3**
Registration date: **2018-12-18, 1397/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-18, 1397/09/27**
Update count: **0**

Registration date
2018-12-18, 1397/09/27

Registrant information

Name
ezatollah sadeghi

Name of organization / entity
kermanshah university of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 83 1427 6325

Email address
dr.makhsosy@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-22, 1397/06/31

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing effect of flow rate of CO2 gas on postoperative complications in laparoscopic surgery

Public title
Assessing effect of flow rate of CO2 gas on postoperative complications in laparoscopic surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ages between 18 and 65 years old Have laparoscopic surgery

Exclusion criteria:
Patients with history of motion sickness, diabetes, cardiovascular failure Patients with concurrent surgery Patients under treatment with narcotic drugs or non-steroidal anti-inflammatory drugs History of severe nausea and vomiting in past surgery

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
The assignment of patients to each group will be applied based on randomization block to control the effect of age and sex. And so on the proportion of sex (women and men) and age (under 40, 40 years old and more) will be approximately the same in the two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patients and the peoples how measuring the variables would be unaware of the presence of patients in the first group and or in the second groups. Only the surgeon aware about grouping, after of ending the evoluation of necessary variables, groups of each person will be spesified in cheklist, based on coding system.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd., Kermanshah

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2018-06-12, 1397/03/22

Ethics committee reference number
IR.KUMS.REC.1397.200

Health conditions studied

1

Description of health condition studied
Flow rate of CO2 gas , Postoperative complications in cholecystectomy laparoscopic surgery

ICD-10 code
K81.0

ICD-10 code description
Acute cholecystitis

2

Description of health condition studied
Flow rate of CO2 gas , Postoperative complications in herniorafi laparoscopic surgery

ICD-10 code
K43

ICD-10 code description
Ventral hernia

Primary outcomes

1

Description
The amount of pain after laparoscopic surgery

Timepoint
1- Immediately after the start of surgery 2- Three months after surgery

Method of measurement
Visual Measurement Scale; VAS

2

Description
The amount of nausea after laparoscopic surgery

Timepoint
1- Immediately after the start of surgery 2- Three months

after surgery

Method of measurement

Visual Measurement Scale; VAS

3

Description

The amount of vomit after laparoscopic surgery

Timepoint

1- Immediately after the start of surgery 2- Three months after surgery

Method of measurement

Visual Measurement Scale; VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: In order to be able to do surgery in the abdomen, in new surgery, they injected some CO2 into the abdominal area, until with the opening of the organs from one another, access is easy for surgeon. Before inserting a laparoscope into the abdomen through the primary port, the peritoneal cavity is fills up with CO2 by an inoculatory device (a device that sends the calculated amount of gas from the gas through a controlled pressure between 18-12 mm Hg into the abdomen). In many cases, determining the flow rate of CO2 gas that can have different effect on organs, done by the surgeon. Speed of entering the gas into the abdominal cavity at the beginning of the laparoscopic surgery is done in both low speed and high speed in according to (L / min CO2). Intervention group: Patients who are eligible for inclusion in the study are included in the study and without knowing that it is only the first group (under the operation with blowing CO2 gas at low speed) or the second group (under the operation with blowing CO2 gas at high speed) , surgery happens to them. In this section, the intervention group 1; people are in the first group.

Category

Treatment - Surgery

2

Description

Intervention: In order to be able to do surgery in the abdomen, in new surgery, they injected some CO2 into the abdominal area, until with the opening of the organs from one another, access is easy for surgeon. Before inserting a laparoscope into the abdomen through the primary port, the peritoneal cavity is fills up with CO2 by an inoculatory device (a device that sends the calculated amount of gas from the gas through a controlled pressure between 18-12 mm Hg into the abdomen). In many cases, determining the flow rate of CO2 gas that can have different effect on organs, done by the surgeon. Speed of entering the gas into the abdominal cavity at the beginning of the laparoscopic surgery is done in both low speed and high speed in according to (L / min CO2). Intervention group: Patients who are eligible for inclusion in the study are included in the study and without knowing that it is only the first group (under the operation with blowing CO2 gas at low speed) or the second group (under the operation with blowing CO2 gas at high speed) , surgery happens to them. In this section, the intervention group 2; people are in the second group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital in Kermanshah

Full name of responsible person

Dr Behnam Reza Makhsosy

Street address

Imam Khomeini Hospital in Kermanshah, Naghliye avenue, Kermanshah

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Postal code

6718743161

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+98 83 3728 5054

Email

ihosp@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

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Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd., Kermanshah

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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

Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Dr Behnam Reza Makhsosy

Position
Managing Director of Imam Khomeini Hospital in Kermanshah

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Imam Khomeini hospital in Kermanshah, Naghliye avenue , Kermanshah

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Kermanshah University of Medical Sciences

Position
Managing Director of Imam Khomeini Hospital in Kermanshah

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Sharmin Rahmani

Position
Researcher of Research Unit, Imam Khomeini Hospital, Kermanshah

Latest degree
Master

Other areas of specialty/work
Biostatistics

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Imam Khomeini hospital in Kermanshah, Naghliye avenue, Kermanshah

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sh.rahmani90@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After the samples being unidentifiable, data is publishable .

When the data will become available and for how long
The access period; Starts 6 months after publishing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used

People who try to help science can use data.

From where data/document is obtainable

Expert of Research Unit of Imam Khomeini Hospital in Kermanshah , Sharman Rahmani , sh.rahmani90@yahoo.com

What processes are involved for a request to access data/document

1- Send a request to sh.rahmani90@yahoo.com 2. The purpose of the data request, stated clearly. 3- If confirmed by the main executor, immediately proceed.

Comments