Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Ventilation on the Procedure of Cholecystectomy by LaparoscopyOn arterial oxygen saturation after surgery

Protocol summary

Study aim
Determining the effect of two methods of ventilation during laparoscopic cholecystectomy on arterial oxygen saturation after surgery

Design
In this study, 104 patients undergoing laparoscopic surgery are divided into two groups. In the first group, the classic method of ventilation is continued. In the second group, in addition to the classical method, PEEP = 3-5 cmH_2 o is used. After surgery the pressure airway surgery, it will be examined.

Settings and conduct
Clinical trial; Kashani Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 60 - 20 years undergoing laparoscopic cholecystectomy. Exclusion criteria: Patients with cardiovascular problems; Patients with pulmonary disease

Intervention groups
In the first group, the classic method of ventilation continues, and in the second group, in addition to the classical method, use PEEP = 3-5 cmH_2 o

Main outcome variables
oxygenation parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181111041607N1**
Registration date: **2018-12-02, 1397/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-02, 1397/09/11**
Update count: **0**

Registration date
2018-12-02, 1397/09/11

Registrant information

Name
Afshar Fazeli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3222 0016

Email address
fazeli.a@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Ventilation on the Procedure of Cholecystectomy by LaparoscopyOn arterial oxygen saturation after surgery

Public title
Effect of Ventilation on the Procedure of Cholecystectomy by LaparoscopyOn arterial oxygen saturation after surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 60 - 20 years undergoing laparoscopic cholecystectomy.

Exclusion criteria:

Patients with cardiovascular disease Patients with pulmonary disease

Age

From **27 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified Random Sampling،Randomization was performed using software and permutable blocks, in which the blocks were 4 and the number was respectively the lowest and the highest in the fourth and first group, and then the third and the second group respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient is not aware of the kind of intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology , Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord,Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718788

Approval date

2016-06-14, 1395/03/25

Ethics committee reference number

IR.SKUMS.REC.1395. 19

Health conditions studied

1

Description of health condition studied

cholelitiasis

ICD-10 code

K80.1

ICD-10 code description

Calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description

oxygen paramerers

Timepoint

after surgery

Method of measurement

palsoximetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in addition to the classical method, PEEP = 3-5 cmH_2 o is used.

Category

Prevention

2

Description

Control group: Receive routine method

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Mahmoud Akhlaghi

Street address

Kashani Hospital of Shahrekord University of Medical Sciences, ParastarAvenue,Shahrekord, Iran

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8818718796

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Email

akhlaghi23@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research and Technology Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Kamal Solati

Street address

Vice Chancellor of Research and Technology Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord,Iran

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8815713471

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solati@skums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor of Research and Technology Shahrekord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Mahmoud Akhlaghi

Position

Assocoate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

Title and more details about the data/document

Laboratory information

When the data will become available and for how long

3 months

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

article

From where data/document is obtainable

journals

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

publication of article

Comments