Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of postoperative peak expiratory flow in open versus laparoscopic cholecystectomy.

Protocol summary

Summary

objectives:The upper abdominal operations change postoperative pulmonary function tests.Laparoscopy causes physiologic changes in the respiratory system too and diaphragmatic function is impaired extensively after laparoscopy. The factors that cause aggravation of restrictive lung disorders increase postoperative lung complications.The thesis objective is examination of Peak Expiratory Flow before , after open and laparoscopic cholecystectomy.Of course better pulmonary function tends to decrease of postoperative pulmonary complications.primary outcome measure is Peak Expiratory Flow. Methods: In this randomized clinical trial thirty ASA class I , II patients with chronic cholecystitis due to gall stone is allocated randomly into group I (open cholecystectomy with 15 patients) and group II (laparoscopic cholecystectomy with 15 patients). The Peak Expiratory Flow (PEF) is measured one day before operation and in recovery room , 24 and 48 hours postoperatively in semisitting position. Collected data is analysed by SPSS. 17 software.Inclusion criteria: age 20-60 years old; symptomatic gall stone and ASAclass 1 & 2. Exclusion criteria: BMI more than 30; emergency surgery; biliary duct stone; acute cholecystitis; positive history of COPD; open cholecystectomy after laparoscopic cholecystectomy and positive history of extensive upper abdominal surgery. Intervention in intervention group is laparoscopic cholecystectomy and in control group is open cholecystectomy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012061710055N1**
Registration date: **2012-08-22, 1391/06/01**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-08-22, 1391/06/01

Registrant information

Name
Mohammad Mehdi Derakhshan
Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1635 7114
Email address
derakhshan.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-02-19, 1390/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of postoperative peak expiratory flow in open versus laparoscopic cholecystectomy.

Public title

Pulmonary function after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20-60 years old; symptomatic gall stone and ASAclass 1 & 2. Exclusion criteria: BMI more than 30; emergency surgery; biliary duct stone; acute cholecystitis; positive history of COPD; open cholecystectomy after laparoscopic cholecystectomy and positive history of extensive upper abdominal surgery.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapour University of Medical Sciences

Street address

golestan runway

City

ahvaz

Postal code

Approval date

2011-04-22, 1390/02/02

Ethics committee reference number

eth-442

Health conditions studied

1

Description of health condition studied

Gall stone

ICD-10 code

K80.2

ICD-10 code description

Cholecystolithiasis

Primary outcomes

1

Description

Peak Expiratory Flow (PEF)

Timepoint

One day before intervention , in recovery room , 24 and 48 hours after intervention

Method of measurement

with peak fiow meter/litre per minute

Secondary outcomes

1

Description

BMI

Timepoint

One day before operation

Method of measurement

Measurment of weight and height /kg per square meter

2

Description

smoking history

Timepoint

One day before operation

Method of measurement

History /pack per year

Intervention groups

1

Description

intervention:laparoscopic cholecystectomy(without abdominal incision,with laparoscope)

Category

Treatment - Surgery

2

Description

control:open cholecystectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan hospital

Full name of responsible person

Mohammad Mehdi Derakhshan

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jondishapour University of Medical Siences
Full name of responsible person
vice-chancellor for research
Street address
Golestan runway
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jondishapour University of Medical Siences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Derakhshan
Position
MD, Anesthesia resident
Other areas of specialty/work
Street address
Golestan runway
City
Ahvaz
Postal code
Phone
+98 61 1222 0168
Fax
Email
derakhshan.m@ajums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jondishapour University of Medical Siences
Full name of responsible person
Mohammad Mehdi Derakhshan
Position
MD, Anesthesia resident
Other areas of specialty/work
Street address
Golestan runway
City
Ahvaz
Postal code
Phone
+98 61 1222 0168
Fax
Email
derakhshan.m@ajums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences
Full name of responsible person
mohammad mehdi derakhshan
Position
anesthesia resident
Other areas of specialty/work
Street address
golestan runway
City
ahvaz
Postal code
Phone
+98 61 1222 0168
Fax
+98 61 1222 0168
Email
derakhshan.m@ajums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty