

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of stress response to laparoscopic cholecystectomy with low or standard intra-abdominal pressure in Shariati Hospital in 1390-1391

Protocol summary

Summary

The main Objective is comparison of indicators of stress response following laparoscopic cholecystectomy with low intra-abdominal pressure compared to the standard intra-abdominal pressure by a a randomized, double-blind, single-center Study in Shariati hospital, Tehran, Iran. We study patients with indication of Laparoscopic Cholecystectomy due to biliary colic who aged 18 years or older, with the American Society of Anesthesiologists (ASA) Physical Status I or II . We Exclude cases with acute cholecystitis, concurrent inflammatory condition like acute pancreatitis, uncured malignancy, major intraoperative or postoperative complications and severe systemic disease. Interventions: 50 patients will be divided randomly into two equal groups: In one group laparoscopic cholecystectomy is done with low intra-abdominal Co2 pressure (8 mmHg) and in the other group with standard intra-abdominal Co2 pressure (14 mmHg). After induction of anesthesia (based on a protocol), patients are allocated to groups according to the random list. Blood Cortisol, blood glucose, CRP and adrenalin will be checked preoperatively, 6 and 24 hours postoperatively. Furthermore, End tidal CO2 and vital signs will be measured at the beginning of the surgery (before entering the gas to the abdomen), each 15 minutes during the surgery and at the end of the operation. the aforementioned items will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110072982N5**

Registration date: **2012-04-11, 1391/01/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-11, 1391/01/23

Registrant information

Name

Zhamak Khorgami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2450

Email address

khorgami@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-06-30, 1391/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of stress response to laparoscopic cholecystectomy with low or standard intra-abdominal pressure in Shariati Hospital in 1390-1391

Public title

Stress response to laparoscopy with low pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) patients aged 18 years or older 2) with diagnosis of biliary colic and 3) ASA class I or II , who were 4) candidate for Laparoscopic cholecystectomy admitted in Shariati hospital, Tehran Exclusion criteria: 1) Cases of acute cholecystitis, 2) concurrent inflammatory condition like acute pancreatitis, 3) uncured malignancy, 4) major intraoperative or postoperative complications and 5) severe systemic disease (ASA class three or greater)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Tehran university of medical sciences

Street address

Central building of Tehran university of medical sciences, Qhods avenue

City

Tehran

Postal code

Approval date

2011-10-15, 1390/07/23

Ethics committee reference number

130/1584/90/3

Health conditions studied

1

Description of health condition studied

Biliary Colic

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

2

Description of health condition studied

stress response

ICD-10 code

R79.9

ICD-10 code description

Abnormal finding of blood chemistry, unspecified

Primary outcomes

1

Description

blood cortisol

Timepoint

preoperatively, 6 and 24 hours postoperatively

Method of measurement

laboratory based on mg/dl

2

Description

CRP

Timepoint

preoperatively, 6 and 24 hours postoperatively

Method of measurement

laboratory based on mg/l

3

Description

blood glucose

Timepoint

preoperatively, 6 and 24 hours postoperatively

Method of measurement

laboratory based on mg/dl

4

Description

blood adrenalin

Timepoint

preoperatively, 6 and 24 hours postoperatively

Method of measurement

laboratory based on pg/ml

Secondary outcomes

1

Description

urine volume

Timepoint

during surgery

Method of measurement

urine bag based on cc

2

Description

heart rate

Timepoint

at the beginning of surgery, every 15 minutes and at the end of the surgery

Method of measurement

monitoring equipment based on pulse rate per minute

3

Description

length of surgery

Timepoint

after surgery

Method of measurement

watch based on minutes

4

Description

end tidal CO2

Timepoint

at the beginning of surgery, every 15 minutes and at the end of the surgery

Method of measurement

Capnography based on mmHg

5

Description

mean arterial pressure

Timepoint

at the beginning of surgery, every 15 minutes and at the end of the surgery

Method of measurement

monitoring equipment based on mmHg

Intervention groups

1

Description

Group 1 (standard intraabdominal pressure):
Laparoscopic cholecystectomy is performed using CO2 with standard intra-abdominal pressure of 14 mmHg.

Category

Treatment - Surgery

2

Description

Group 2 (Low intraabdominal pressure): Laparoscopic cholecystectomy is performed using CO2 with low intra-abdominal pressure of 8 mmHg.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Zhamak Khorgami

Street address

Shariati Hospital, North Kargar Avenue,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhonzade

Street address

Research deputy, Medicine faculty, Poursina avenue,
Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences - Shariati Hospital

Full name of responsible person

Zhamak Khorgami

Position

General Surgeon / faculty of surgery department

Other areas of specialty/work

Street address

Shariati Hospital, North Kargar Avenue

City

Tehran

Postal code

Phone

+98 21 8490 2450

Fax

+98 21 8863 3039

Email

khorgami@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences - Shariati hospital

Full name of responsible person

Zhamak Khorgami

Position

General Surgeon / faculty of surgery department

Other areas of specialty/work

Street address

Shariati Hospital, North Kargar Avenue

City

Tehran

Postal code

Phone

+98 21 8490 2450

Fax

+98 21 8863 3039

Email

khorgami@gmail.com

Web page address

Person responsible for updating data

Contact

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