Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Single-incision laparoscopic cholecystectomy and mini-laparoscopic cholecystectomy in Shariati hospital between 2012 to 2014: A Randomized Clinical Trial Study

Protocol summary

Summary

The aim of this study is the comparison between mini-laparoscopic cholecystectomy (MLC) and single-incision laparoscopic cholecystectomy (SILC). This study is a randomized clinical trial conducted on the patients admitted to Shariati Hospital of Tehran that diagnosed with chronic cholecystitis, symptomatic cholelithiasis, with indications for laparoscopic cholecystectomy. The exclusion criteria included: ages more than 60, having CBD stone, obesity (BMI equal or more than 40), acute cholelithiasis, and previous surgeries in the upper abdominal areas. 40 patients with symptomatic cholelithiasis who met the criteria will be enrolled in the study. After obtaining informed consent, they will be randomly assigned to SILC or MLC (20 in each group). The duration of the surgery and the events occurring during the surgery will be registered. Also, the two groups will be compared in terms of levels of pain (with visual analog scale: VAS), hospitalization period, the postsurgical complications including wound infection, and postoperative nausea and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206072982N10**
Registration date: **2015-09-04, 1394/06/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-04, 1394/06/13

Registrant information

Name

Zhamak Khorgami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8490 2450

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Single-incision laparoscopic cholecystectomy and mini-laparoscopic cholecystectomy in Shariati hospital between 2012 to 2014: A Randomized Clinical Trial Study

Public title

Comparison of Single-incision laparoscopic cholecystectomy and mini-laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patients being admitted in Tehran

Shariati Hospital with symptomatic cholelithiasis who are candidates of laparoscopic cholecystectomy. Exclusion criteria: ages more than 60; having Common Bile Duct stone, obesity (BMI equal or more than 40), acute cholelithiasis, and previous surgeries in the upper abdominal areas.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Tehran University of Medical Sciences

Street address
Surgery department, Imam khomeini hospital, Keshavarz boulvard

City
Teharn

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
10234

Health conditions studied

1

Description of health condition studied
Calculus of gallbladder without cholecystitis

ICD-10 code
K80.2

ICD-10 code description
Any condition listed in K80.5 with cholangitis

Primary outcomes

1

Description
duration of durgery

Timepoint
from the time the skin was cut until the time it was closed.

Method of measurement
recorded by surgeon

Secondary outcomes

1

Description
pain after surgery

Timepoint
8, 16, and 24 hours after surgery

Method of measurement
measuring levels of pain using visual analog scale(VAS)

2

Description
Nausea and vomiting after surgery

Timepoint
in the first 24 hours after surgery

Method of measurement
subjective, recorded by observer from the questionnaire

3

Description
intraoperative complications

Timepoint
at the end of operation

Method of measurement
recorded by surgeon

4

Description
Medical complications after surgery: hypertension, ischemia or cardiac arrhythmia

Timepoint
at the time of discharge

Method of measurement
based on medical chart

5

Description
hernia at the site of incisions

Timepoint
12 months after after surgery

Method of measurement
clinical exam and imagings

6

Description

wound infection

Timepoint

up to 1 month after surgery

Method of measurement

office visits and medical charts

7

Description

Postoperative narcotic usage for pain control

Timepoint

up to 48 hours after surgery

Method of measurement

recorded by nurse in the questionnaire

8

Description

Total Length of wounds

Timepoint

at the end of operation

Method of measurement

ruler with one millimeter percision

Intervention groups

1

Description

In the MLC group, a 10- millimeter port was placed in the lower area of the navel, a 2.7- millimeter port was placed in the epigastric region, a 2.7-millimeter port was placed 2 centimeters below the ribs, and another 2.7- millimeter port was placed in the lower right side of the anterior axillary line. A 10- millimeter camera was sent in from the first port and the grasper holding the fundus of the gallbladder was sent in through the last port. The gallbladder was then taken out from the 10- millimeter port. After the laparoscopic cholecystectomy, the patients underwent the recovery period of the operating room and were transferred to the ward. Paracetamol was used as the base pain reliever and was given to the patients for 48 hours, 1 gram every 8 hours. In case of severe pain, 25 grams of Pethidine was slowly injected into the vein.

Category

Treatment - Surgery

2

Description

In the SLIC Group: the main port was placed in the lower area of the navel, and the graspers and camera was entered through same port and cholecystectomy was performed. Then, the gallbladder was taken out from the navel location. The fascia and skin will be closed at the site of navel.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital, General Surgery Ward

Full name of responsible person

Dr. Zhamak Khorgami

Street address

General Surgery Ward, 3rd. Floor, Shariati Hospital, North Kargar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Office of Research & Technology Management

Street address

6th. Floor, Central Organization of Tehran University of Medical Sciences, Quds St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of 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

Dr. Zhamak Khorgami

Position

General Surgeon / faculty of surgery department

Other areas of specialty/work

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Person responsible for scientific inquiries

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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