

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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)

##### Phone

+98 21 8490 2450

##### Email address

khorgami@tums.ac.ir

##### 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 boulevard

**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**

**Street address**

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**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**

Dr. Zhamak Khorgami

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## Person responsible for updating data

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Tehran University of Medical Sciences - Shariati hospital

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## 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*