

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of perioperative Outcomes following four port, three port and single incision laparoscopic cholecystectomy in patients of shariati hospital in 2011

Protocol summary

Summary

This study compares perioperative outcomes between 3-port, 4-port and single incision laparoscopic cholecystectomy. In this double-blind randomized clinical trial, 90 patients are randomly assigned into 3 equal groups with 3-port, 4-port or single-incision laparoscopic cholecystectomy. The duration of surgery and intraoperative events is recorded. After surgery, intensity of pain (based on visual analog scale) and received intravenous analgesics, length of hospital stay, postoperative complications including wound infection, nausea and vomiting will be recorded and compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105152982N4**
Registration date: **2011-12-23, 1390/10/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-23, 1390/10/02

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

University grant for Clinical Residency Thesis, Tehran University of Medical Sciences

Expected recruitment start date

2011-06-01, 1390/03/11

Expected recruitment end date

2011-12-31, 1390/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of perioperative Outcomes following four port, three port and single incision laparoscopic cholecystectomy in patients of shariati hospital in 2011

Public title

Comparison of perioperative Outcomes following four-port, three-port and single incision laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Indication for laparoscopic cholecystectomy, Informed consent for participating in the study Exclusion Criteria: Severe inflammation of gallbladder, Bile duct stone needing bile exploration, Drug addiction, planned surgery not progressed

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

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, Qhods avenue

City

Tehran

Postal code

Approval date

2010-12-06, 1389/09/15

Ethics committee reference number

1106 / 130 / 89 / د

Health conditions studied

1

Description of health condition studied

cholecystitis

ICD-10 code

K81.9

ICD-10 code description

(کله سیستیت، مشخص نشده (حاد یا مزمن

Primary outcomes

1

Description

postoperative narcotic usage

Timepoint

Continuously recorded and measured at the time of discharge

Method of measurement

Patient controlled analgesia device

Secondary outcomes

1

Description

postoperative nausea and vomiting

Timepoint

12 hours intervals till discharge

Method of measurement

History taking

2

Description

wound infection

Timepoint

At the time of discharge and 7 days later

Method of measurement

Physical examination

3

Description

intraoperative adverse events

Timepoint

At the end of surgery

Method of measurement

Questionnaire for the surgeon

4

Description

Surgeon opinion about surgery difficulty

Timepoint

At the end of surgery

Method of measurement

Questionn to the surgeon with likert scale

5

Description

post operathve Hospital stay

Timepoint

At the time of discharge

Method of measurement

based on medical reocords

6

Description

Patient's satisfaction about cosmetic outcome

Timepoint

3 months after surgery

Method of measurement

Question with likert scale

7

Description

Other systematic postoperative complication

Timepoint

At the time of discharge and 30 days later

Method of measurement

History taking and clinical records

8

Description

Postoperative pain

Timepoint

6 hours intervals for 24 hours

Method of measurement

Visual analogue scale

9

Description

Surgery duration

Timepoint

At the end of surgery

Method of measurement

Stopwatch

10

Description

Bile leakage or bile duct trauma

Timepoint

At the time of discharge and 30 days later

Method of measurement

Clinical records

Intervention groups

1

Description

Control group(4 port): In this group, 4 laparoscopic port are used for cholecystomy. 10-mm port in the umbilicus, 5 mm port in epigastric area (sub-xiphoid), 5 mm port in midclavicular line about 2 cm below the costal margine and the last 5 mm port is placed in the right lower quadrant at the anterior axillary line. Camera is inserted from the first 10-mm port into the abdomen and other instruments are inserted from other ports. Perioperative outcomes are assessed during and after surgery.

Category

Treatment - Surgery

2

Description

Intervention group 1 (3 port cholecystectomy): In this group one 10-mm port in inserted from the umbilical area and two 5 mm ports are inserted in epigastric area (sub-xiphoid) and right midclavicular line about 2 cm below the costal margin respectively. Camera is inserted from the 10-mm port and other instruments are inserted from another ports. the principals of cholecystectomy is the same as other groups. Perioperative outcomes are assessed during and after surgery.

Category

Treatment - Surgery

3

Description

Intervention group 2 (Single incision laparoscopic cholecystectomy): In this group a 2 cm vertical incision is made in the umbilicus and all three ports (one 10-mm and two 5-mm ports) are inserted from the umbilical area. The camera is entered from the 10-mm port and other instruments are inserted from other ports. The principals of cholecystectomy is the same as other groups. Perioperative outcomes are assessed during and after surgery.

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

در قالب بودجه پایان نامه دستیار تخصصی

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Zhamak Khorgami

Position

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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