ISRCTN50339464 https://doi.org/10.1186/ISRCTN50339464

Comparing two types of keyhole surgery for gallbladder removal: A clinical trial

Submission date
09/09/2024

Recruitment status
No longer recruiting

Registration date
11/09/2024

Overall study status
Completed

Last Edited
18/10/2024

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to compare two different methods of performing keyhole surgery for removing the gallbladder in patients with gallstones. The first method, known as conventional laparoscopic cholecystectomy (CLC), uses three small instruments to ensure a safe view of the surgical area. The second method, called two ports plus one puncture laparoscopic cholecystectomy (TPPOP LC), uses a slightly different technique that involves fewer entry points but still provides a clear view for the surgeon. The study will compare the outcomes of these two methods to determine if the new approach is as safe and effective as the standard one.

Who can participate?
Patients aged 12 - 80 years who have gallstones causing symptoms and require gallbladder removal surgery can participate in this study. Participants should be classified as ASA I or II, which means they are either healthy or have only mild, controlled health conditions.

What does the study involve?
Participants will undergo one of two types of keyhole surgery to remove the gallbladder. They will be randomly assigned to either the conventional laparoscopic cholecystectomy (CLC) or the two ports plus one puncture laparoscopic cholecystectomy (TPPOP LC). All participants will receive the standard care and monitoring before, during, and after surgery.

What are the possible benefits and risks of participating?
The conventional laparoscopic surgery is the current standard method and has a low risk of complications, such as wound infections, pain, bleeding, or injury to nearby structures like the bile duct, bowel, or liver. There is a small chance (1% to 2%) of injury to the bile duct, and in rare cases, the surgery may need to be converted to an open procedure (less than 1%).
The newer two ports plus one puncture approach may involve a slightly longer operation time but could reduce the number of incisions. However, it also carries similar risks of complications, including wound infections, pain, bleeding, and injury to nearby structures, with a bile duct injury rate of 1% to 3%. If complications occur, the surgery may need to be switched to the conventional method (around 5.45% of cases) or to an open surgery (about 0.18% of cases).

Where is the study run from?
The study is being conducted at the No. (1) Military Hospital (700 bedded) in Pyin Oo Lwin, Myanmar.

When is the study starting and how long is it expected to run for?
April 2019 to September 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Min Nay Zar Wyke, minnayzarwyke3681@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Min Nay Zar Wyke

ORCID ID
https://orcid.org/0009-0005-0986-1047

Contact details
Yay Chan Oe Quater, Block 12
Pyin Oo Lwin
Myanmar
05081
+95 95501867
minnayzarwyke3681@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Conventional versus two ports plus one puncture laparoscopic cholecystectomy: A clinical trial

Study objectives
Two ports plus one puncture laparoscopic cholecystectomy is as safe and effective as conventional laparoscopic cholecystectomy.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 14/11/2019, Ethical Review Committee, Defence Services Medical Academy (No. 94, D-1, Pyay Road, Mingalardon, Yangon, 11021, Myanmar; +95 03135062; registrardsma@gmail.com), ref: 11/Ethics 2018

Study design
Single-center hospital based interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Two ports plus one puncture laparoscopic cholecystectomy is as safe and effective as conventional laparoscopic cholecystectomy.

Interventions
This is a hospital-based, interventional, randomized controlled study that was carried out over a period of 21 months in a surgical unit at No. (1) Military Hospital (700 bedded) in Pyin Oo Lwin, Myanmar. All patients with symptomatic gallstones who were treated by laparoscopic cholecystectomy were included in the study. Patients with ASA III, IV & V, previous upper abdominal surgery, common bile duct pathology, clinical or USG suspected gall bladder cancer, and bleeding disorders were excluded from the study. Patients were evaluated using a detailed history, a thorough physical examination, and investigations such as liver function tests, a complete blood picture, urea, creatinine, viral serology, and abdominal sonography. An informed written consent explaining the research procedure was obtained at least one day before surgery. The patients were randomized into group A (CLC) (n = 49) and group B (TPPOP LC) (n = 49).
In conventional laparoscopic cholecystectomy, the procedure will be done with four ports which will be placed 10 mm port in the subumbilical region, another 10 mm port in the subxiphoid epigastric region, 5 mm port in the right subcostal midclavicular line and another 5 mm port in the right subcostal anterior axillary line location.
In two ports plus one puncture laparoscopic cholecystectomy, the procedure will be done with two ports, which will be placed 10 mm port in the subumbilical region, 5 mm port in the subxiphoid epigastric region, and with 2.3 mm alligator grasper which will be punctured below the right costal margin.
The end points of this research were to compare operation time, intraoperative complications, conversion rate, postoperative pain, postoperative complications, and postoperative hospital stay. Statistics were analyzed on a total of 98 patients by using SPSS software package version 28.0. The categorical data was calculated by the statistical method Chi-square. For continuous variables, the statistical significance of patients was analyzed by two independent Student’s t tests.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Measured using patient records unless noted otherwise:
1. The operation time is noted from the time of skin incision to the last stitch of skin closure.
2. Intraoperative complications including bile duct injury, bowel injury, vascular injury, and injuries to nearby structures are observed in all cases during operation.
3. Postoperative pain is measured using a visual analogue scale (VAS) within 12 hour, 24 hour, 36 hour and 48 hour.
4. Rescue analgesia is added with injection of intravenous tramadol 1mg/kg if VAS is more than 4 and/or if the patient suffers breakthrough pain or if the patient complains of pain between the assessments.
5. Postoperative complications like prolonged ileus and wound infection in all cases are observed daily during the hospital stay.
6. The duration of a hospital stay is measured from the time it takes from the date of surgery to the date of discharge based on the discharge criteria.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2021

Eligibility

Key inclusion criteria
All patients with symptomatic gall stones with ASA I & II

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
80 years

Sex
All

Total final enrolment
98

Key exclusion criteria
1. Patients with ASA III, IV & V
2. Previous upper abdominal surgery
3. Patients with common bile duct pathology

4. Patients with clinical or USG suspected gall bladder cancer
5. Patients with bleeding disorders

Date of first enrolment
01/12/2019

Date of final enrolment
31/07/2021

Locations

Countries of recruitment
Myanmar

Study participating centre
No. (1) Military Hospital (700 Bedded)
Block 7
Pyin Oo Lwin
Myanmar
05081

Sponsor information

Organisation
Defence Services Medical Academy

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
Min Nay Zar Wyke
Email: minnayzarwyke3681@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			11/09/2024	No	Yes
Protocol file			11/09/2024	No	No