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Surgical Techniques: Robotic versus conventional Laparoscopic cholecystectomy IN benign Gallbladder disease (STARLING Trial)

Submission date
02/10/2025

Recruitment status
Recruiting

Registration date
02/10/2025

Overall study status
Ongoing

Last Edited
02/10/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Robot-assisted surgery is increasingly used for gallbladder removal, even though no randomized trials have directly compared it with conventional keyhole (laparoscopic) surgery. Previous studies suggest there may be no major differences in complications or recovery between these two minimally invasive techniques. This study aims to determine whether robot-assisted surgery is at least as safe and effective as standard laparoscopic surgery for patients with benign gallbladder conditions.

Who can participate?
Adults aged 18 years with benign gallbladder conditions who need surgery and meet the study eligibility criteria.

What does the study involve?
Patients will be randomly assigned to either robot-assisted or standard laparoscopic surgery. The study will look mainly at complications within 30 days after surgery. Other measures include recovery outcomes, health care use, quality of life reported by the patient, and cost-effectiveness. Follow-up occurs at 7 and 30 days after surgery.

What are the possible benefits and risks of participating?
There are no additional risks or benefits from participating in this study, as both surgical techniques are already routinely used in our centre.

Where is the study run from?
Queen Alexandra Hospital (UK)

When is the study starting and how long is it expected to run for?
Feburary 2025 to June 2026

Who is funding the study?
Intuitive Foundation (USA)

Who is the main contact?
Mr. G.I. van Boxel, g.vanboxel@nhs.net

Study website
https://starlingtrial.uk

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333268

ClinicalTrials.gov number
NCT07119203

Secondary identifying numbers
CPMS 67756

Study information

Scientific Title
Surgical Techniques: Robotic versus conventional Laparoscopic cholecystectomy IN benign Gallbladder disease (STARLING Trial)

Acronym
STARLING

Study objectives
The primary objective of this study is to determine whether robotic multiport cholecystectomy is non-inferior to conventional laparoscopic cholecystectomy in terms of morbidity and complications occurring within 30 days postoperatively. Secondary objectives are to compare both procedures with respect to perioperative outcomes and patient recovery, patient-reported outcome measures (PROMs) such as health-related quality of life and patient satisfaction, as well as healthcare utilization and costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/04/2025, London – Hampstead Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)2071048171, +44 (0)207 104 8284; Hampstead.rec@hra.nhs.uk), ref: 25/LO/0297

Study design
Randomized; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Robotic versus conventional laparoscopic cholecystectomy in benign gallbladder disease

Interventions
The STARLING trial is a randomised clinical trial comparing robotic multi-port cholecystectomy with conventional laparoscopic cholecystectomy. We hypothesize that robotic multi-port cholecystectomy is, at least, as safe as conventional laparoscopic cholecystectomy with regards to morbidity and complications within 30 days after surgery.

Robotic surgery for cholecystectomy is increasingly being applied. Previous observational studies showed promising results, but the studies are small, limited by selection bias and most studies include patients that were operated during the learning curve of robotic surgery. A prospective randomized trial, in a hospital setting where the learning curve has been completed will allow for true comparison of robotic multiport cholecystectomy to conventional laparoscopic cholecystectomy.

Conventional laparoscopic cholecystectomy, or multi-port keyhole surgery or the gallbladder, is the current gold standard for treatment of benign gallbladder disease, and this will be the control arm for the trial. All adult (>18 years) patients, presenting with benign gallbladder disease can be included in the study. For specific in- and exclusion criteria, please see the appropriate section.

This study is estimated to take 12 months to complete. We expect to need about 8 months for inclusions, an additional month is needed to collect all follow-up assessments. With over 500 elective cholecystectomies performed annually in our Trust, we expect this to be ample time to obtain all 276 inclusions. The final three months are allocated to perform the analyses and draft manuscripts.

Laparoscopic and robotic cholecystectomy are already commonly applied in PHU. Given our literature review and experience with both procedures within the Trust, in combination with the short time span of the trial, an interim analysis is not deemed contributory. Upon finalizing the trial inclusions, we aim to complete analyses and report within 4 months.

The research team is aware of risks of bias and has discussed this trial with various stakeholders, ranging from patients, research facilitators, specialist nurses and fellow surgeons, to ensure the protocol measures outcomes of interest to all stakeholders. We've ensured all participating surgeons are at least two standard deviations over the learning curve threshold, equal theatre lists will be allocated with regards to robotic and laparoscopic cholecystectomy, so all surgeons will perform an equal number of procedures in each arm. The procedures in this trial will be performed as extra lists, so the trial will not take away training opportunities for residents in our normal theatre program.

Collected data includes baseline characteristics (age, gender, BMI, comorbidities), preoperative workup (bloods, imaging), procedural outcomes (duration of surgery, blood loss), postoperative recovery (% same day discharge), complication and pain (pain medication needed in recovery). Patient reported outcome measures include EuroQoL 5D, Quality of Recovery and Otago Condition Specific Questionnaire. Data will be collected using RedCap. Based on a systematic review of the literature (Straatman et al. 2023), we expect robotic cholecystectomy to be at least non-inferior to conventional laparoscopic cholecystectomy with regards to postoperative complications (7.9% in RC and 7.8% in LC). With a p-value of 0.05 and power of 90%, 250 patients will need to be included. We corrected for 10% of loss to follow-up, making for a total of 276 patients will be included in the study.

Patients will be approached during their visit to the surgical outpatient department. They will be informed on the trial and receive the patient information leaflet. The following week the research team will call the patient to confirm whether the patient would like to participate. The patient will be randomized over the phone, to allow for allocation to the appropriate theatre lists. Informed consent and randomization will be performed using RedCap.

As mentioned before, the research team has sat down with various stakeholders. Patients advise was sought during a specialised clinic, where patients who were listed for gallbladder surgery were also asked to fill out a questionnaire. The questionnaire revealed that all patients were happy to participate in such a trial, and that the outcomes of interest for patients were; complications, recovery after surgery and pain. These outcomes are the main outcomes for our trial. Similarly, we have sought patient advise on our protocol and information leaflets via our PPI facilitator. Volunteers from the PPI team have assessed our patient information sheets and provided feedback which was incorporated.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
30-day complications and morbidity, taking into account any complication as graded by the Clavien-Dindo classification. Data on all complications will be recorded, allowing for comparison

of the frequency of complications, severity of individual complications and in the case of multiple complications: assessment of the comprehensive complication index number for each patient.

Secondary outcome measures

1. Duration of the procedure (minutes): Two time intervals will be recorded to assess procedure duration and robotic set-up times:
1.1. Total time spent in the operating theatre, measured as the time from patient arrival (hh:mm) to exit (hh:mm).
1.2. Actual surgical time, measured as the time from skin incision ("knife to skin") to skin closure (hh:mm).
Times will be recorded in minutes.
2. Peri-operative blood loss (millilitres) measured quantitatively in millilitres. Additionally, the number of tonsil swabs used during the procedure will be recorded as a qualitative indicator of blood loss.
3. Intra-abdominal pressure (mmHg) during surgery continuously measured in millimeters of mercury (mmHg) during insufflation throughout the surgical procedure.
4. Incidence (%) of gallbladder perforation during surgery: The percentage (%) of surgical procedures in which perforation of the gallbladder occurs intraoperatively.
5. Incidence (%) of intraoperative complications: Percentage (%) of patients experiencing any intraoperative complication during surgery.
6. Technical difficulty of the procedure graded according to Nassar classification
7. Intraoperative assessment of the liver parenchyma, classified into one of the following categories based on visual and tactile evaluation by the surgeon: normal, enlarged, steatotic, or cirrhotic.
8. Percentage (%) of surgical procedures during which imaging-based assessment of the common bile duct (CBD) was performed. Assessment is defined as the use of on-table cholangiogram (OTC) or intraoperative ultrasound (IOUSS) for visualization of the CBD.
9. Among patients in whom gallstones were identified in the common bile duct (CBD) during intraoperative assessment, the percentage (%) of cases in which CBD exploration was performed.
10. Use of peri-operative antibiotics. According to current guidelines, prophylactic antibiotics are not routinely indicated. Any deviations, including type, dose, and timing of antibiotics given during surgery, will be recorded.
11. Incidence (%) and number of drains placed during surgery. In cases with multiple drains, the total number of drains placed will be recorded.
12. Surgical perceived effort measured by Surgical Task Load Index (SURG TLX)
13. Amount and type of analgesia administered to the patient in the post-anesthesia care unit (recovery room) from arrival until discharge from recovery. Data includes all analgesic medications given and their dosages from arrival in recovery room until discharge from recovery.
14. Documentation of whether opioids were prescribed at the time of hospital discharge, including type, dose, and quantity, measured on day of discharge.
15. Percentage (%) of patients discharged from the hospital on the same calendar day as their surgical procedure, measured from surgery until discharge on the same day.
16. Duration in minutes from the patient's departure from the operating theatre to arrival in stage 3 recovery
17. Percentage (%) of patients who are readmitted to the hospital for any cause within 30 days following surgery
18. Percentage (%) of patients requiring any additional medical or surgical interventions within 30 days following cholecystectomy
19. Health-related quality of life measured by EuroQol 5D-5L (EQ-5D-5L) at baseline

(preoperative), on the day of hospital discharge, at 7 days postoperatively, and at 30 days postoperatively
20. Gallstone-specific quality of life measured by Otago Condition-Specific Questionnaire (O-CSQ) at baseline (preoperative) and at 30 days postoperatively
21. Quality of recovery measured by Quality of Recovery 15 (QoR-15) questionnaire at hospital discharge, 7 days postoperatively, and 30 days postoperatively
22. Cost-effectiveness based on hospital costs within 30 days after surgery. To assess the impact of implementing robotic cholecystectomy (RC) on hospital costs, case data will be collected and compared between the RC and laparoscopic cholecystectomy (LC) groups. This includes operative costs, admission costs, and additional treatment costs (total healthcare utilization) from the index operation up to 30 days postoperatively.

Overall study start date
09/02/2025

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. Age equal or above 18 years
2. Diagnosis of benign gallbladder disease (gallstones or gallbladder polyp) as proven on imaging (ultrasound scan and/or magnetic resonance cholangiopancreatography)
3. Capacity to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 276; UK Sample Size: 276

Key exclusion criteria
1. Minimally invasive procedure is not deemed possible by the operating surgeon
2. Evidence of acute cholecystitis, requiring acute surgery
3. Known stones in the common bile duct at time of surgery
4. Suspicion of possible malignancy
5. Pregnancy
6. Diagnosis of liver cirrhosis, stage III or IV
7. Insufficient language skills to be able to perform the quality-of-life questionnaires

Date of first enrolment
18/08/2025

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
England

United Kingdom

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Intuitive Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets used and/or analyzed during the current study can be made available by the chief /principal investigator upon reasonable request and in agreement with the research collaboration and data transfer guidelines of the PHU.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	16/04/2025	02/10/2025	No	Yes