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A study comparing recovery outcomes between enhanced recovery care and conventional care after keyhole gynaecological surgery

Submission date
01/11/2025

Recruitment status
No longer recruiting

Registration date
15/11/2025

Overall study status
Completed

Last Edited
14/08/2026

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The introduction of minimally invasive surgery has had a major impact on gynaecological surgery. Initially, laparoscopic surgery was introduced for diagnostic purposes, and it has evolved to provide more complex therapeutic procedures. Nowadays, minimally invasive surgery has become the standard management of a wide range of gynaecological conditions worldwide. Undoubtedly, laparoscopic surgery has been proven to provide the benefits such as faster recovery, shorter hospitalization and quicker return to daily activities compared to laparotomy surgery. Along with good surgical technique and modern advances in surgical devices, a multidisciplinary team's good perioperative care is crucial for a good surgical outcome.
Early Recovery After Surgery program (ERAS) was introduced with the goal of enhancing postoperative recovery using evidence-based practices. ERAS integrates perioperative management to minimize surgical stress, enable a quicker return to physiological state, and faster recovery. Minimally invasive surgery is one of the key elements in the enhanced recovery after surgery program. There is mounting evidence showing ERAS implementation improves in surgical outcomes in patient who undergo bowel surgery and open gynaecological surgery. Therefore, it remains an question whether enhanced recovery pathways benefit patients undergoing laparoscopic surgery for benign gynaecological conditions where minimally invasive techniques have already been incorporated.
This study aims to explore the surgical outcome of integrating ERAS models into laparoscopic gynaecological surgery for benign gynaecological conditions compared to conventional surgical care.

Who can participate?
Patients aged 18-65 years undergoing elective benign laparoscopic gynaecological surgery

What does the study involve?
Patients will be randomly allocated into two groups to receive either the ERAS care model or the conventional care model.
In the ERAS care model, during the preoperative counselling will be involving setting expectation for recovery and discharge plan. Prolonged preoperative fasting is avoided, the

patient is allowed solid food up to 6 hours before the operation and fluids up to 2 hours before surgery and a carbohydrate drink is provided 2 hours before surgery. Surgical site infection prevention includes cleaning the skin and vaginal area with chlorhexidine 4%. Mechanical prophylaxis is encouraged. Intraoperatively, anaesthetist implements opioid-sparing or opioid-free multimodal analgesia. No intravenous fluids are administered prior to the surgery. Intravenous fluids are administered intraoperatively with the aim of maintaining euvolaemia and are discontinued at the end of procedure.
In the conventional care model, the preoperative counselling will not involve in setting expectation and discharge plan. Patients are required to fast from midnight before surgery, and a carbohydrate drink is not provided. Intravenous fluid will be administered once patient kept nil by mouth. The skin is cleaned with povidone, while the vaginal area is cleaned with chlorhexidine 4%. Mechanical prophylaxis is not used. Intraoperatively, opioids are used, and intravenous fluids continue post-surgery until subjects are able to tolerate oral intake.
After uncomplicated surgery, patients will be monitored in ward for early postoperative complications and recovery. In both groups, patients are advised to inform doctor for assessment once they are feel well enough to be discharged. Additionally, postoperative assessment of pain score, postoperative nausea and vomiting, initiation of ambulation in ward, and tolerance of feeding will be carried out by doctor not involved in research study at 6 hours, 12 hours, during specialist ward round or upon request as standard management of postoperative review in the study center until the patient meets the discharge criteria.
Patients who fulfilled the following criteria are allowed to be discharged:
1. Stable vital signs
2. Absence of early postoperative complications
3. Ability to tolerate oral fluids or meals
4. Ambulation in the ward
5. Well controlled post-operative pain
The time of fit-for-discharge will be recorded in the hospital's electronic medical record. Patients will be advised to return to the hospital if any complications arise after discharge. Follow-up appointments will be scheduled in 2 weeks after the operation to review at the clinic and 1month post-operation via telephone to assess for postoperative complications or readmission.

What are the possible benefits and risks of participating?
Potential benefits:
1. Improved patient outcomes: Enhanced recovery care have been shown to reduce postoperative complications, shorten hospital stays, and enhance the overall recovery experience for patients.
2. Enhanced quality of life: Patients may experience reduced pain, improved mobility, and faster return to their daily activities, which can positively impact their quality of life.
3. Healthcare resource utilization: Successful implementation of enhanced recovery after surgery care can lead to reduced healthcare costs and more efficient resource allocation within the healthcare system.
Potential risks:
1. Changes in perioperative care: The risk of unintended consequences or complications arising from changes in perioperative care with the implementation of enhanced recovery after surgery care.
2. Ethical considerations related to informed consent and patient autonomy.

Where is the study run from?
Hospital Putrajaya (hospital with specialist) (Malaysia)

When is the study starting and how long is it expected to run for?
November 2023 to November 2024

Who is funding the study?
Hospital Putrajaya, Ministry of Health Malaysia

Who is the main contact?
Dr Ng Chien Huey, chien@live.com.my

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
NMRR ID-23-02447-S12

Study information

Scientific Title
A randomized controlled trial comparing outcomes in patients undergoing laparoscopic benign gynaecological procedure with enhanced recovery after surgery (ERAS) care versus conventional care

Study objectives
To evaluate the outcome of enhanced recovery after surgery (ERAS) care compared with conventional care in patients undergoing laparoscopic benign gynaecological procedure

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 10/11/2023, Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) (Kompleks Institut Kesihatan Negara (NIH) No.1, Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam,, Shah Alam, Selangor, 40170, Malaysia; +60 (0)333628398/8399 /8404/8408; mrecsec@moh.gov.my), ref: NMRR ID-23-02447-S12

2. Approved 08/11/2023, The Research Ethics Committee, The National University of Malaysia (Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Muhriz, Pusat Perubatan UKM, Jalan Yaacob Latif, Bandar Tun Razak,, Cheras, Kuala Lumpur, 56000, Malaysia; +60 (0)39145 5048 / 5046; sepukm@ukm.edu.my), ref: JEP-2023-612

Primary study design
Interventional

Study design
Open-label prospective randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Perioperative care in minimally invasive gynaecological surgery

Interventions
A randomized controlled trial comparing outcomes in patients undergoing laparoscopic benign gynaecological procedure with enhanced recovery after surgery (ERAS) care versus conventional care.

This is a single-centre, open-label, prospective randomized controlled trial. All patients undergoing elective benign laparoscopic gynaecological surgery in Hospital Putrajaya, Malaysia, who fulfilled inclusion and exclusion criteria and consented will be recruited into the study from 1st November 2023 till 30th November 2024. Patients will be randomised into two groups (receiving either the ERAS care model or the conventional care model) in a 1:1 ratio. Randomization will be done by an independent person not involved in the research study using an Excel randomization formula, to create a list and the sequence will be placed in sealed opaque envelopes.

The model of perioperative care (ERAS model and conventional care) will include pre-operation (before surgery), intra-operation (during the surgery), and post-operation (after surgery).

In the ERAS care model, during the preoperative counselling will be involving setting expectation for recovery and discharge plan. Prolonged preoperative fasting is avoided, subject is allowed solid food up to 6 hours prior to operation and fluids up to 2 hours prior to surgery

and carbohydrate drink is provided 2 hours before surgery. Surgical site infection prevention includes cleaning the skin and vaginal area with chlorhexidine 4%. Mechanical prophylaxis is encouraged. Intraoperatively, anaesthetist implements opioid-sparing or opioid-free multimodal analgesia. No intravenous fluids are administered prior to the surgery. Intravenous fluids are administered intraoperatively with the aim of maintaining euvolaemia and are discontinued at the end of procedure.

In conventional care model, the preoperative counselling will not involve in setting expectation and discharge plan. Subjects are required to fast from midnight before surgery, and a carbohydrate drink is not provided. Intravenous fluid will be administered once patient kept nil by mouth. The skin is cleaned with povidone, while the vaginal area is cleaned with chlorhexidine 4%. Mechanical prophylaxis is not used. Intraoperatively, opioids are used, and intravenous fluids continue post-surgery until subjects are able to tolerate oral intake.

After uncomplicated surgery, subjects will be monitored in ward for early postoperative complications and recovery. Assessment will be carried out by doctor not involved in research study at 6hours interval, during specialist ward round or upon request as standard management of postoperative review in the study centre until the subject meets the discharge criteria.

Follow-up appointments will be scheduled in 2 weeks after the operation to review at the clinic and 1-month post-operation via telephone to assess for postoperative complications or readmission.

Intervention Type
Mixed

Primary outcome(s)
Postoperative length of stay, from completion of surgery to time documented meet the fit-for-discharge criteria

Key secondary outcome(s)
1. Postoperative pain measured using numerical rating scale at 6 hours and 12 hours post operation
2. Readmission rate within 30 days, follow up subject until 30 days post operation
3. Postoperative complications defined according to Clavien-Dindo classification from post operation till 1 month post operation

Completion date
30/11/2024

Eligibility

Key inclusion criteria
1. Women who are scheduled for elective laparoscopic surgery with benign gynaecological indication in the form of procedure salpingectomy, salpingo-oopherectomy, ovarian cystectomy, myomectomy or hysterectomy with or without bilateral salpingo-oophorectomy)
2. American Society of Anesthesiologist (ASA) classification I-II
3. Aged 18-65 years
4. Distance between patient’s home and hospital less than 50 km radius

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
57

Key exclusion criteria
1. Malignancy
2. Pregnancy
3. Logistic problem and residence out of 50 km radius
4. Intellectual disability, impaired cognition
5. Allergic to drug in study protocol
6. History of anesthesia complication
7. Sleep apnea
8. Poorly controlled asthma and chronic obstructive pulmonary disease
9. On therapeutic anticoagulation
10. History of arrhythmia, congestive heart failure, pacemaker or hypertension require more than three medications
11. Type 1 Diabetes mellitus, poorly control Type 2 Diabetes mellitus where HbA1c >7.9%
12. Significant underlying kidney disease (eGFR <30 mL/min/1.73m2)
13. Liver cirrhosis
14. Daily alcohol consumption more than 2 drinks

Date of first enrolment
01/12/2023

Date of final enrolment
05/08/2024

Locations

Countries of recruitment
Malaysia

Study participating centre

Hospital Putrajaya
Pusat Pentadbiran Kerajaan Persekutuan, Presint 7
Wilayah Persekutuan Putrajaya
Malaysia
62250

Sponsor information

Organisation
Hospital Putrajaya

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Putrajaya

Funder Name
Kementerian Kesihatan Malaysia

Alternative Name(s)
Ministry of Health Malaysia, KKM, MOH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Chien Huey Ng (chien@live.com.my)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			14/08/2026	No	No
Plain English results			14/08/2026	No	Yes
Protocol file			14/08/2026	No	No
Statistical Analysis Plan			14/08/2026	No	No