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Improving recovery in repeat laparoscopic surgery for bile duct stones using a modern care protocol

Submission date
22/03/2025

Recruitment status
No longer recruiting

Registration date
07/04/2025

Overall study status
Ongoing

Last Edited
31/03/2025

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
Surgery for bile duct stones can be challenging, especially in patients who have had previous operations. This study looks at whether a modern recovery protocol called "enhanced recovery after surgery" (ERAS) can help patients recover faster and more comfortably after repeat laparoscopic bile duct surgery.

Who can participate?
Adults aged 18 and over with confirmed extrahepatic bile duct stones and a history of biliary surgery, where endoscopic treatment was not successful.

What does the study involve?
Participants are randomly assigned to one of two groups. One group receives standard surgical care, while the other receives enhanced recovery care, including shorter fasting, early movement and feeding, and better pain control. Both groups undergo the same laparoscopic surgery.

What are the possible benefits and risks of participating?
Participants in the ERAS group may experience faster recovery and less discomfort. All procedures follow standard medical practices, and no unusual risks are expected.

Where is the study run from?
The Second Affiliated Hospital of Soochow University, China.

When is the study starting and how long is it expected to run for?
June 2017 to December 2025

Who is funding the study?
The Scientific Pre-research Foundation of the Second Affiliated Hospital of Soochow University, China

Who is the main contact?
Dr Lin Changjie, 631118863@qq.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Application of enhanced recovery after surgery in the secondary surgery of extrahepatic bile duct stones

Study objectives
Primary Aim:
To assess whether enhanced recovery after surgery (ERAS) protocols improve postoperative recovery, reduce inflammation and complications, and shorten hospital stay in patients undergoing laparoscopic biliary reoperation for extrahepatic bile duct stones.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/07/2024, Ethics Committee of the Second Affiliated Hospital of Soochow University (1055 Sanxiang Road, Suzhou, 215004, China; +86 512-6828-9999; sdfeylunli@163.com), ref: JD-LK2024-47-101

Study design
Single-center double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Enhancing recovery surgery (ERAS) protocols after laparoscopic biliary reoperation for extrahepatic bile duct stones

Interventions
The patients were randomly divided into the ERAS group and the control group by block randomization with 30 cases in each group. The random numbers were generated by computer and allocated in a 1:1 ratio. The designer prepared random number envelopes and distributed them to the clinical doctors. The entire experimental process was without contact with the patients. Similarly, the clinical doctors responsible for patient enrollment, intervention implementation, and result analysis did not participate in the randomization process.

ERAS Group: Patients received perioperative care following ERAS principles, including shortened fasting, carbohydrate loading, no routine nasogastric tube or bowel prep, early oral feeding and ambulation, controlled fluids, multimodal analgesia, and early removal of drains.
Control Group: Patients received standard perioperative management, including prolonged fasting, traditional bowel prep, nasogastric decompression, delayed oral intake and ambulation, routine drain management, and conventional analgesia.

Intervention Type
Mixed

Primary outcome measure
Pain intensity measured using the Faces Pain Scale – Revised at 6, 12, 18, 24, 48, and 72 hours postoperatively.

Secondary outcome measures

1. Time to first anal ventilation (hours) recorded postoperatively
2. Postoperative hospital stay (days) recorded from surgery to discharge
3. Hospitalization costs in RMB collected from medical records at discharge
4. Serum C-reactive protein (CRP) measured via blood test on postoperative days 1, 3, and 5
5. Serum prealbumin (PAB) measured via blood test on postoperative days 1, 3, and 5
6. Incidence of complications (nausea, vomiting, bile leakage, infection, etc.) recorded during hospital stay

Overall study start date
01/06/2017

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. MRCP confirmed presence of extrahepatic bile duct stones with multiple stones and large diameters
2. There was a history of biliary tract surgery in the past, including cholecystectomy or biliary tract exploration
3. After confirmation by the gastroenterology doctor, ERCP could not remove the stones at one time
4. The extrahepatic bile duct is dilated with a diameter larger than 8 mm

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. The diameter of extrahepatic bile duct is less than 8 mm
2. The number of extrahepatic bile duct stones is small, and their diameters are also small, and ERCP is expected to be able to remove all of them at one time
3. Severe cardiopulmonary dysfunction
4. History of choledochojejunostomy surgery

Date of first enrolment
01/06/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
China

Study participating centre
The Second Affiliated Hospital of Soochow University
China
215004

Sponsor information

Organisation
Second Affiliated Hospital of Soochow University

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.sdfey.com/web/jsp/front/english.jsp

ROR
https://ror.org/02xjrkt08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Second Affiliated Hospital of Soochow University

Alternative Name(s)
The Second Affiliated Hospital of Soochow University, Second Affiliated Hospital of Suzhou University, General Hospital of Nuclear Industry, Sino-French Friendship Hospital,

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date