

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/03/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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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

Department of General Surgery, Suzhou

Jiangsu

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sdfeyjg@163.com

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