

# A clinical study on the direction of bile flow in patients with non-jaundice common bile duct stones

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<b>Registration date</b> 10/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/01/2024	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Even though it's common for certain gallstone problems not to cause jaundice (yellowing of the skin), we don't fully understand why. People often think it's because the bile duct isn't completely blocked. This seems reasonable, but it doesn't explain everything.

This study looked at how bile (a digestive fluid) moves in these cases, using special scans called magnetic resonance cholangiopancreatography and selective intraoperative cholangiography before and during surgery to figure this out.

This study will give us a better overall view of how bile flows, helping us understand why jaundice might not happen in gallstone cases. It also helps doctors decide on the best treatment.

### Who can participate?

Patients with anicteric choledocholithiasis admitted to the Department of Hepatobiliary Surgery of Hainan General Hospital from January 2019 to July 2023.

### What does the study involve?

Preoperative magnetic resonance cholangiopancreatography and intraoperative cholangiography were performed to determine the direction of bile flow in all patients.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

Hainan General Hospital (China)

### When is the study starting and how long is it expected to run for?

June 2019 to July 2023

Who is funding the study?  
Hainan Provincial Department of Science and Technology (China)

Who is the main contact?  
Professor Yunfu Lv, yunfu\_lv@126.com

## Contact information

### Type(s)

Principal Investigator

### Contact name

Prof Yunfu Lv

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

YSPTZX202005

# Study information

## Scientific Title

Classification and treatment of anicteric choledocholithiasis based on the patterns of bile flow into the duodenum

## Study objectives

The absence of jaundice in these patients may be due to the passage of bile into the duodenum through a specific path.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 20/12/2018, The medical ethics committee of Hainan general hospital (No.19 Xiuhua road, Xiuying district, Haikou, 570311, China; +86 898-68622476; meng@hnsrmyy14.wecom.work), ref: Med-Eth-Re[2018] 81

## Study design

Observational cohort study

## Primary study design

Observational

## Secondary study design

Cohort study

## Study setting(s)

Hospital

## Study type(s)

Diagnostic, Treatment

## Participant information sheet

No participant information sheet available (retrospective study)

## Health condition(s) or problem(s) studied

Choledocholithiasis

## Interventions

Current interventions as of 19/01/2024:

Patients with anicteric choledocholithiasis were admitted to the Department of Hepatobiliary Surgery of Hainan General Hospital from January 2019 to July 2023. Preoperative magnetic resonance cholangiopancreatography (MRCP) and intraoperative cholangiography (IOC) were performed to determine the direction of bile flow in all patients.

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Previous interventions:

Patients with anicteric choledocholithiasis were admitted to the Department of Hepatobiliary Surgery of Hainan General Hospital from January 2019 to December 2022. Preoperative magnetic resonance cholangiopancreatography (MRCP) and intraoperative cholangiography (IOC) were performed to determine the direction of bile flow in all patients.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

Direction of bile flow measured using MRCP detection and intraoperative cholangiography pre operation.

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

20/12/2018

### **Completion date**

31/07/2023

## **Eligibility**

### **Key inclusion criteria**

1. Patients with choledocholithiasis and bile duct dilatation (diameter  $\geq 8$  mm)
2. No jaundice to the naked eye and total serum bilirubin  $\leq 34$   $\mu\text{mol/L}$
3. Informed consent

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

25 Years

### **Upper age limit**

86 Years

### **Sex**

Both

### **Target number of participants**

130

**Total final enrolment**

103

**Key exclusion criteria**

1. Patients without choledocholithiasis or bile duct dilatation
2. Jaundice visible to the naked eye or serum total bilirubin > 34  $\mu\text{mol/L}$
3. Congenital choledochal cyst, bile duct tumor, ampullary tumor, and pancreatic head cyst and tumor

**Date of first enrolment**

03/01/2019

**Date of final enrolment**

31/12/2022

**Locations****Countries of recruitment**

China

**Study participating centre****Hainan general hospital**

No.19 Xiuhua Road

Xiuying district

Haikou

China

570311

**Sponsor information****Organisation**

Hainan General Hospital

**Sponsor details**

No.19 Xiuhua Road

Xiuying district

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China

570311

+86 898-68622476

kjc@hainmc.edu.cn

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.php.com.cn/>

**ROR**

<https://ror.org/030sr2v21>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Hainan Provincial Department of Science and Technology

**Alternative Name(s)**

, Department of Science and Technology of Hainan Province

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

China

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/12/2024

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study will be available upon request from Professor Yunfu Lv.

[Yunfu\\_lv@126.com](mailto:Yunfu_lv@126.com)

**IPD sharing plan summary**

Available on request