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

Submission date
08/08/2023

Recruitment status
No longer recruiting

Registration date
10/08/2023

Overall study status
Completed

Last Edited
19/01/2024

Condition category
Digestive System

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

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

Study type(s)
Diagnostic, Treatment

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

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Patients with choledocholithiasis and bile duct dilatation (diameter ≥ 8 mm)
2. No jaundice to the naked eye and total serum bilirubin ≤ 34 μmol/L
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
86 years

Sex
All

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 μmol/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
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Sponsor information

Organisation
Hainan General Hospital

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

Individual participant data (IPD) sharing plan
The datesets generated and/or analysed during the current study will be available upon request from Professor Yunfu Lv.
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IPD sharing plan summary
Available on request