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Does prophylactic antibiotics reduce infectious complications post endoscopic retrograde cholangio pancreatography in common bile duct stones patients: a clinical trial?

Submission date
22/04/2025

Recruitment status
Recruiting

Registration date
01/05/2025

Overall study status
Ongoing

Last Edited
01/05/2025

Condition category
Surgery

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure used to diagnose and treat problems in the bile and pancreatic ducts. One common issue it addresses is stones in the common bile duct. However, ERCP can be risky and may lead to complications like pancreatitis, bleeding, perforation, and infections. Infections can occur in 5% to 18% of cases and are responsible for about 7.8% of deaths related to ERCP complications. To reduce infection risks, some methods have been suggested, such as using fewer contrast injections, lowering bile duct pressure, ensuring complete drainage, and using preventive antibiotics. However, the use of preventive antibiotics is debated because it can lead to antibiotic resistance, which is a growing global problem. Major medical societies recommend antibiotics only in specific cases, but the evidence supporting this is not strong. This study aims to find out if using preventive antibiotics can lower infection rates after ERCP in patients with bile duct stones.

Who can participate?
Adults over 18 years old who:
Have common bile duct stones diagnosed by ultrasound, CT scan, or MRI.
Show no signs of cholangitis (no fever and normal white blood cell count).
Are in good general health (classified as ASA Physical Status I or II).

What does the study involve?
Participants will be patients with bile duct stones who need ERCP but do not have cholangitis. They will be randomly assigned to one of three groups:
Prophylactic Antibiotic Group: Will receive Amikacin (an antibiotic) before the ERCP procedure.
Full-dose Antibiotic Group: Will receive Amikacin and a third-generation cephalosporin antibiotic from before the ERCP until hospital discharge.
Control Group: Will not receive antibiotics, only normal saline.
After ERCP, patients will be monitored for signs of infection through symptoms and lab tests.

What are the possible benefits and risks of participating?
This study may help promote the appropriate use of antibiotics during ERCP in patients with common bile duct stones. As a result, it could reduce antibiotic resistance in the community, as well as lower healthcare costs and shorten hospital stays.
The main risk of this study is the possibility of allergic reactions in the group receiving antibiotics. In the group not receiving antibiotics, there may be a higher risk of post-ERCP infectious complications.

Where is the study run from?
The study is being run at the 108 Military Central Hospital in Hanoi, Vietnam.

When is the study starting and how long is it expected to run for?
December 2022 to December 2025

Who is funding the study?
108 Military Central Hospital, Hanoi, Vietnam.

Who is the main contact?
1. Prof. Nguyen Lam Tung
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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
337/QD-VNC

Study information

Scientific Title
Prophylactic antibiotics reduce infectious complications post endoscopic retrograde cholangio pancreatography in common bile duct stones patients

Study objectives
Prophylactic antibiotics reduce the infectious complications post Endoscopic Retrograde Cholangio Pancreatography intervention in common bile duct stones patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/12/2022, Ethics Committee of the 108 Military Central Hospital (No. 1 Tran Hung Dao, Bach Dang Ward, Hai Ba Trung District, Hanoi, 100000, Viet Nam; +84 1900986869; bvtuqd108@benhvien108.vn), ref: 6893

Study design
Interventional open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Prevention of infectious complications post endoscopic retrograde cholangio pancreatography in common bile duct stones patients

Interventions
The study plans to enroll approximately 240 patients with common bile duct stones without signs of cholangitis at the time of hospital admission. All patients have an indication for ERCP stone extraction and randomly assigned to one of three study groups.

• Prophylactic Antibiotic Group
+ Medication: Amikacin
+ Administration: Amikacin at a dose of 15 mg/kg, diluted in 0.9% NaCl to a total volume of 100 mL, administered via intravenous infusion over 60 minutes
+ Timing: Administered 60 minutes before ERCP procedure. For patients with renal impairment, the Amikacin dose will be adjusted based on glomerular filtration rate (GFR).
+ Other Names: Antibiotic prophylaxis

• Full-dose Antibiotic Group
+ Medications: Amikacin + Third-generation Cephalosporine
+ Administration: Amikacin at 15 mg/kg/day in combination with Cefoperazone 2 g twice daily, administered by slow intravenous injection every 12 hours
+ Timing: From before the ERCP procedure until hospital discharge, typically lasting 4–7 days.

• Control Group: No Antibiotics Group
+ Medication: normal saline
+ Administration: No antibiotics administered. Patients will receive an intravenous infusion of normal saline on the day of the procedure.

Participants were randomly assigned to one of the three groups using a simple randomization method in which the remainder of their record number divided by 3 determined the group allocation

Intervention Type
Procedure/Surgery

Primary outcome measure
Infectious complications measured through examining the patients and assessing clinical symptoms such as fever, abdominal pain, and jaundice at ...

Secondary outcome measures
1. Complete blood count (CBC) is measured using a CBC test at hospital admission and 24–48 hours after the ERCP procedure
2. GOT is measured using a GOT test at hospital admission and 24–48 hours after the ERCP procedure
3. GPT is measured using a GPT test at hospital admission and 24–48 hours after the ERCP procedure
4. GGT is measured using a GGT test at hospital admission and 24–48 hours after the ERCP

procedure
5. ALP is measured using an ALP test at hospital admission and 24–48 hours after the ERCP procedure
6. Total bilirubin is measured using a total bilirubin test at hospital admission and 24–48 hours after the ERCP procedure
7. Direct bilirubin is measured using a direct bilirubin test at hospital admission and 24–48 hours after the ERCP procedure
8. Amylase is measured using an amylase test at hospital admission and 24–48 hours after the ERCP procedure
9. Lipase is measured using a lipase test at hospital admission and 24–48 hours after the ERCP procedure
10. CRP is measured using a CRP test at hospital admission and 24–48 hours after the ERCP procedure
11. Procalcitonin is measured using a procalcitonin test at hospital admission and 24–48 hours after the ERCP procedure

Additional tests are performed if abnormal signs or changes are observed until clinical condition stabilizes and discharge from the hospital

Overall study start date
31/12/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Patients with common bile duct stones are diagnosed by abdominal ultrasound, endoscopic ultrasound, CT scan, or abdominal MRI.
2. No signs of cholangitis at the time of admission, defined by the following criteria:
2.1. Non fever (temperature < 37°C)
2.2. White blood cell count between 4 G/L and 10 G/L
2.3. Good general condition, classified as ASA Physical Status I or II

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
240 patients, estimated 80 patients with each group.

Key exclusion criteria
1. Patients with severe coagulopathy (INR > 1.5 or platelet count < 50 G/L)
2. Patients with severe systemic illnesses, such as unstable myocardial infarction, respiratory failure, or circulatory failure
3. Patients with duodenal perforation or failed ERCP due to inability to access the papilla
4. Patients with active infections in other organ systems requiring antibiotic therapy
5. Patients have received any systemic antibiotics within 48 hours prior to the ERCP procedure
6. Patients are allergic to antibiotics used in the study

Date of first enrolment
31/12/2022

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Viet Nam

Study participating centre
108 Military Central Hospital
No. 1 Tran Hung Dao, Bach Dang Ward, Hai Ba Trung District
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Sponsor information

Organisation
108 Military Central Hospital

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Sponsor type
Hospital/treatment centre

Website
http://benhvien108.vn/home.htm

ROR
https://ror.org/04k25m262

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
108 Military Central Hospital

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 datasets generated during and/or analysed during the current study will be available upon request from (Thanh Tran Van, vanthanh260290@gmail.com)
- The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	English		01/05/2025	No	Yes
Participant information sheet	Vietnamese		01/05/2025	No	Yes
Protocol file			01/05/2025	No	No