

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: July 12, 2020

ClinicalTrials.gov ID: NCT03701009

Study Identification

Unique Protocol ID: Saline irrigation in ERCP

Brief Title: Saline Irrigation Reduces the Residual Bile Duct Stones During Endoscopic Retrograde Cholangiopancreatography (ERCP)

Official Title: Saline Irrigation Reduces the Residual Bile Duct Stones After ERCP: a Single-arm Prospective Study

Secondary IDs:

Study Status

Record Verification: July 2020

Overall Status: Completed

Study Start: October 10, 2018 [Actual]

Primary Completion: July 1, 2020 [Actual]

Study Completion: July 1, 2020 [Actual]

Sponsor/Collaborators

Sponsor: Hepatopancreatobiliary Surgery Institute of Gansu Province

Responsible Party: Sponsor

Collaborators:

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: LDYYMENG2018-1028

Board Name: Ethics Committee of The First Hospital of Lanzhou University

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Data Monitoring: Yes

Study Description

Brief Summary: The purpose of this study was to evaluate the usefulness of saline solution irrigation in decreasing residual common bile duct (CBD) stones.

Detailed Description: In recent years, ERCP is the standard procedure to remove the bile duct stones. The big stones(>1.2 cm) require additional lithotripsy procedures for complete stone removal. Nevertheless, small stone fragments still remain in the common bile duct when the cholangiogram shows normal. The fragments are too small to be verified. These retained fragments may cause recurrence of stones. Another way to demonstrate residual CBD stones is to use intraductal ultrasonography (IDUS). However, IDUS has limited availability in clinical practice. The single-operator cholangioscopy (SOC)-system Spyglass gains widespread acceptance because of its independent washing channels and direct viewing. The investigators used Spyglass to detect if saline(50 or 100ml) infusion might clear the bile duct fragments after ERCP. Saline irrigation has many advantages such as easy stone removal, no additional cost and rare side effects. The purpose of this study is to evaluate the usefulness of saline solution irrigation in decreasing residual CBD stones.

Conditions

Conditions: Stone Clearance

Keywords: ERCP
Common bile duct stone
Cholangitis
Residual stone
Irrigation

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 47 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Stone removal (Saline 50ml each time) After CBD stone removal via lithotripsy, and the cholangiogram showed normal, residual CBD stones were detected by SpyGlass in the first round, if CBD not clean, sterile saline 50ml were intermittently irrigated into the CBD. After that, if bile duct clearance was not achieved, another 50ml saline will be irrigated	Procedure/Surgery: CBD stone removal via lithotripsy Hold saline irrigation just after X-ray demonstrated no stone residue, a Spyglass explored. Procedure/Surgery: Saline 50ml If not clean, intermittent saline irrigation 50ml, and Spyglass explored second time. Procedure/Surgery: Saline +50ml

Arms	Assigned Interventions
into CBD again until the clear bile duct determined by SpyGlass.	If still have some stone fragments, intermittent saline irrigation another 50ml after the second Spyglass detection, Spyglass explored third time to evaluate stone clearance.

Outcome Measures

Primary Outcome Measure:

1. Stone fragments clearance
Type 1: Not clean, large stone fragments; Type 2: Clusters residue and floccule; Type 3: Small biliary sludge or floccule
Type 4: Slightly clean with a small amount of floccule or small residue; Type 5: Clean.

[Time Frame: 3 months]

Secondary Outcome Measure:

2. Post-ERCP cholangitis
Number of Post-ERCP cholangitis participants, Post-ERCP cholangitis was defined as a temperature of more than 38 °C for 24–48 h after the procedure, thought to have a biliary cause without evidence of other concomitant infections.

[Time Frame: 3 months]

3. Bleeding
Number of Bleeding participants as who was defined as the clinical and endoscopic evidence of hemorrhage associated. with a decreasing the hemoglobin level >2 g/dl.

[Time Frame: 3 months]

4. Post-ERCP pancreatitis
Number of Post-ERCP pancreatitis participants who was defined as any new or worsened abdominal pain with an increasing serum. amylase of over three times the upper normal limit that was measured more than 24h after the procedure.

[Time Frame: 3 months]

5. Perforation
Number of perforation participants who was defined as the presence of air or contrast in the retroperitoneal space.

[Time Frame: 3 months]

6. The procedure time
Was defined as the sum of times of all processes of endoscopic procedure.

[Time Frame: 3 months]

Eligibility

Minimum Age: 18 Years

Maximum Age: 90 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- ERCP common bile duct stone patients were able to provide written informed consent;
- Size of stone large than 1.2 cm.

Exclusion Criteria:

- Unwillingness or inability to consent for the study;
- Coagulation dysfunction (INR> 1.5) and low peripheral blood platelet count ($50 \times 10^9 / L$) or using anti-coagulation drugs;
- Previous ERCP;
- Prior surgery of Bismuth #, Roux-en-Y and Cholangiojejunostomy;
- Preoperative coexistent diseases: acute pancreatitis, GI tract hemorrhage or perforation, severe liver disease (such as decompensated liver cirrhosis, liver failure and so on), septic shock;
- Biliary-duodenal fistula confirmed during ERCP;
- Pregnant women or breastfeeding;
- Presence of intrahepatic duct stone;
- Malignancy.

Contacts/Locations

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IPDSharing

Plan to Share IPD: No

References

Citations: Ahn DW, Lee SH, Paik WH, Song BJ, Park JM, Kim J, Jeong JB, Hwang JH, Ryu JK, Kim YT. Effects of Saline Irrigation of the Bile Duct to Reduce the Rate of Residual Common Bile Duct Stones: A Multicenter, Prospective, Randomized Study. *Am J Gastroenterol.* 2018 Apr;113(4):548-555. doi: 10.1038/ajg.2018.21. Epub 2018 Mar 27. PubMed 29610513

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Links:

Available IPD/Information: