Comparing the Efficacy and Safety of Holmium Laser Lithotripsy Versus Electrohydraulic Lithotripsy for the Treatment of Difficult Choledocholithiasis and Pancreatic Duct Stones

NCT07418112

Status	RECRUITING
Phase	Phase 4
Sponsor	Rush University Medical Center
Enrollment	40 participants

Plain Language Summary

This study compares two methods for breaking up and removing stubborn stones in the bile duct or pancreatic duct that are hard to treat with standard techniques: holmium laser lithotripsy (using laser energy) versus electrohydraulic lithotripsy (using electrical shock waves), both delivered through a thin scope.

You may be eligible if...
- You are 19 to 85 years old
- You have one or more bile duct or pancreatic duct stones considered "difficult" (e.g., larger than 15 mm, impacted, or irregularly shaped)
- You have signed informed consent

You may NOT be eligible if...
- Your stones can be removed with standard methods
- You fall outside the age range
- You have contraindications to the procedure

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (7)

- Age 19-85 years
- Signed written informed consent.
- Presence of one or more biliary (common bile duct or intrahepatic) or pancreatic duct stones that are deemed "difficult" based on at least one of the following criteria:
- Stone diameter e 15 mm in any single dimension as measured on prior cross-sectional imaging (CT, MRCP, or EUS).
- Presence of an impacted stone that cannot be dislodged with a standard balloon or basket.

... and 2 more (see full listing online)

Exclusion (8)

- Pregnancy: Repeated ERCP would be delayed until after delivery if possible
- Clinically significant, uncorrectable coagulopathy (defined as INR \> 1.5 or platelet count \< 50,000/µL).
- Surgically altered upper gastrointestinal anatomy that precludes conventional ERCP access (e.g., Roux-en-Y gastric bypass), unless an alternative access route (e.g., laparoscopy-assisted or EUS-directed) is planned as the standard of care.
- Known or highly suspected malignant biliary or pancreatic stricture associated with the stone.
- Acute pancreatitis at the time of screening, unless it is gallstone pancreatitis with persistent biliary obstruction, for which ERCP is therapeutically indicated.

... and 3 more (see full listing online)

Locations (1 total)

Rush University Medical Center, Chicago, Illinois, United States