

Trial Description

Title

"Short access" cholangioscopy (SAC) vs. direct transnasal cholangioscopy (TNC) with ultra-slim endoscopes for diagnosis and therapy of cholangiopathies

Trial Acronym

Cholangioscopy

URL of the trial

http://none

Brief Summary in Lay Language

Cholangioscopy is an established technique that allows direct visualization of the bile ducts and performance of diagnostic and therapeutic procedures. The standard cholangioscopy involves access into the bile duct with a so called "mother-baby" technique. Using this technique a very slim cholangioscope ("baby") is advanced through the working channel of a standard duodenoscope ("mother") into the common bile duct. However, this method is expensive and cumbersome.

very lately 2 new cholangioscopy techniques were proposed :

- 1.) The "short access" cholangioscopy is a modified "mother-baby" technique. A modification of the duodenoscope (distal access port for the working channel) allows a application of a short cholangioscopy device.**
- 2.) Direct cholangioscopy with a high resolution ultra-slim video endoscopes without use of a "mother-baby" technique. This technique offers the advantage of a high resolution image and the wider working-channel allows adequate biopsies and therapeutic interventions.**

The present studies compares both novel techniques

Brief Summary in Scientific Language

Cholangioscopy is an established technique that allows direct visualization of the bile ducts and performance of diagnostic and therapeutic procedures. The standard cholangioscopy involves access into the bile duct with a so called "mother-baby" technique. Using this technique a very slim cholangioscope ("baby") is advanced through the working channel of a standard duodenoscope ("mother") into the common bile duct. However, this method is a 2-men procedure, the equipment is expensive and the procedure is cumbersome .

Very lately 2 new cholangioscopy techniques were proposed :

- 1.) The "short access" cholangioscopy is a modified "mother-baby" technique. A modification of the duodenoscope (distal access port for the working channel) allows an application of a short cholangioscopy device that leads to improved maneuverability of the device.**

2.) Direct cholangioscopy with a high resolution ultra-slim video endoscopes without use of a "mother-baby" technique. This technique is a 1-man procedure that offers the advantage of high resolution imaging. Additionally the 2 mm working channel allows sampling of adequate biopsies and therapeutic interventions like electrohydraulic lithotripsy, argon plasma ablation and direct stent placement.

Nevertheless, access to the bile ducts with ultra-slim endoscopes can be difficult and reported success rates vary from 55 - 95 %.

The present studies compares both novel techniques

Organizational Data

- DRKS-ID: **DRKS00003082**
- Date of Registration in DRKS: **2011/05/10**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **FF108/2010 , Ethikkommission der Landesärztekammer Hessen**

Secondary IDs

Health condition or Problem studied

- ICD10: **C22.1 - Malignant neoplasm: Intrahepatic bile duct carcinoma**
- ICD10: **K80 - Cholelithiasis**

Interventions/Observational Groups

- Arm 1: **Direct TNC**
The ultra-slim endoscope is (EG 530NP, Fujinon Inc., Saitama, Japan)s advanced into the duodenum via the transnasal route. Under direct visual and fluoroscopic control a balloon catheter is advanced into a branch of the intrahepatic bile duct and the balloon was inflated to anchor it within the duct. Afterwards, the endoscope is advanced over the balloon catheter into the common bile duct using a ropeway method.
Successful TNC is defined as the advancement of the endoscope into the bifurcation of the biliary tree or the strictured segment. Complications, such as perforation, cholangitis, pancreatitis, and bleeding are assessed. We also evaluate the usefulness of direct TNC in diagnostic procedures such as endobiliary forceps biopsy and therapeutic procedures such argon plasma coagulation.



The endoscope EG 530NP was not provided by Fujinon for the purpose of this study.

■ Arm 2: **"Short access" Cholangioscopy (SAC)**

A short "baby" is introduced through the working channel of a standard duodenoscope and advanced into the common bile duct under fluoroscopic and visual control. Successful SAC is defined as the advancement of the endoscope into the bifurcation of the biliary tree or the strictured segment. Complications, such as perforation, cholangitis, pancreatitis, and bleeding are assessed. We also evaluate the usefulness of direct TNC in diagnostic procedures such as endobiliary forceps biopsy and therapeutic procedures such as argon plasma coagulation.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Successful evaluation of the whole common bile duct during cholangioscopy. A successful procedure is defined as a cholangioscopy with advancement of the endoscope up to the hilar bifurcation or to the stenotic segment within the bile duct

Secondary Outcome

- 1.) time requirements for procedure (measurement with a clock)**
- 2.) Perinterventional complications (cholangitis, perforation)**
- 3.) Time for intubation of the bile duct**
- 4.) Correlation between endoscopic prediction of intraductal stenoses and histological assessment.**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/06/01**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **81 Years**

Additional Inclusion Criteria

Follow-up after stone removal
Evaluation of biliary stricture
Adenomas of the papilla with suspected ductal involvement
Removal of retained common bile duct stones
A previous endoscopic sphincterotomy is a prerequisite for inclusion

Exclusion criteria

Patients with a diffuse stricture of the distal common bile duct
bleeding tendency (international normalized ratio > 1.5 or platelet count < 50,000/mL)
Patients with evidence of pancreatic cancer
Patients with surgical altered anatomy
Patients with contraindications for ERCP were excluded.

Addresses

- **Primary Sponsor**
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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/03/30**

Trial Publications, Results and other documents

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*