Prospective, Multi-center, Randomized Controlled Study Comparing Endoscopic Clearance of Non-Complex Biliary Stones Using Fluoroscopy/Radiation-Free Direct Solitary Cholangioscopy (DSC) to Standard of Care Endoscopic Retrograde Cholangiography (ERC)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bile duct disorders
Study type	Interventional

Summary

ID

NL-OMON49021

Source
ToetsingOnline

Brief title
Non-Complex Biliary Stones DSC vs. ERC RCT

Condition

- Bile duct disorders

Synonym
Bile duct stones, Choledocholothiasis

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Corporation
Source(s) of monetary or material Support: Boston Scientific Corporation

Intervention

Keyword: (ERC), Direct Solitary Cholangioscopy (DSC), Endoscopic Retrograde Cholangiography, Non-complex biliary stone, Radiation-free

Outcome measures

Primary outcome

Complete stone clearance by extraction of bile duct stones from the common bile

duct (CBD) into duodenum as determined by

fluoroscopy free cholangioscopy in the DSC arm and by cholangiography in the

ERC arm.

Secondary outcome

Evaluation of occurrence of SAEs between DSC arm vs ERC arm

radiation exposure between DSC arm vs ERC arm

Duration procedure DSC arm vs ERC arm

Study description

Background summary

A hybrid endoscopic/radiological procedure, endoscopic retrograde cholangio-pancreatography (ERCP), remains the predominant diagnostic and therapeutic modality. Given the inevitable evolution of technology, it is possible in the future, that as with other GI luminal organs, direct endoscopic

evaluation of the bile duct with cholangioscopy may replace cholangiography for the evaluation and management of at least some kinds of biliary disease. Non-complex biliary stone disease represents a potential such disease process, suitable for study.

Study objective

The aim of this study is to prospectively assess the benefits and effectiveness of non-complex gallstone clearance
fluoroscopy / radiation-free direct solitary cholangioscopy (DSC) comparing the SpyGlass * system to non-complex biliary stone clearance using standard endoscopic retrograde cholangiography (ERC).

Study design

A total of 250 patients will be randomized on a 1:1 ratio. Block randomization through an
online database system will be used. Randomization will be stratified by study center. Prior
to randomization, each participating endoscopist at each of the participating centers must
perform up to 10 Roll-in cases. These roll-in cases will not count towards the enrollment
ceiling of 250 cases.

* Prospective
* Consecutive cases
* Multi-center
* Randomized 1:1 ratio:
o Group A (ERC arm): Clearance of bile duct stones using standard-of-practice ERCP techniques
o Group B (DSC arm): Clearance of bile duct stones using DSC techniques
o Block-randomization by site
* Non-inferiority hypothesis
* Validation of stone clearance by ERC in DSC arm and by DSC in ERC arm.

Intervention

Cross-over study wherein arm A the non-complex gallstones are first removed with solitary cholangioscopy (DSC) using the SpyGlass * and clearance is checked with endoscopic retrograde cholangiography (ERC) and in arm B the non-complex gallstones are first removed by standard endoscopic retrograde cholangiography (ERC) and removal is checked with solitary cholangioscopy (DSC) (SpyGlass *).

Study burden and risks

Nature and extent of burden:
* Prior to the procedure:
Demography; Non-invasive imaging results; Medical history; Results

of blood tests In the practice/clinic of your doctor

* During the procedure:
Realization of the cannulation part of the procedure;

Number and size of the stones that are removed;

The total exposure of the patient to radiation;

The volume of contrast fluid used during the procedure;

Total number of additional devices/resources used during the procedure;

The result of the procedure; stones removed yes or no;

Assessment of serious side effects

* After the procedure (24 hours after procedure): Telephone assessment of serious adverse event

* Follow-up visits (7 days after the procedure): Telephone assessment of serious adverse event

* End of the study (30 days after the procedure): Telephone assessment of serious adverse event

Possible risks of your participation
Risks have been associated with ERCP procedures including but not limited to:
* Pancreatitis
* Infection
* Perforation
* Bleeding
* Allergic reaction to contrast fluid

Patients participating in this study run the same risks as all patients who undergo a procedure with the SpyGlass * DS but who do not participate in the study.

The potential risks and side effects associated with the SpyScope * DS Access and Delivery catheter include:
* Pancreatitis
* Light pancreatitis

* Self-restricted pancreatitis
* Stomach ache
* Persistent DSC-related bacteremia
* Cholangitis
* Unexpected hospitalization
* Fever
* Perforation
* Light perforation
* Bleeding after EST
* Self-restricted abdominal pain
* Asymptomatic amylasemia
* Bleeding
* Hemobilia
* Aspiration pneumonia
* Infection

The potential risks and side effects associated with the SpyGlass * Retrieval Basket include:
* Pancreatitis after ERC
* Cholangitis
* Bleeding
* Broken basket and impaction

There may also be other risks or side effects that are currently unknown.

You can ask your doctor about the risks of participating in this study. Your doctor may also ask you to sign other necessary consent forms for the procedures you are undergoing.

Risks of pregnancy in this study
Pregnant women and women who intend to become pregnant during the study are excluded from this study. This procedure has not been studied in pregnant women. There may be extra risks for you (or for your embryo / fetus) if you become pregnant or if you are breast-feeding. Such extra risks are not known at this time. Tell your doctor immediately if you are pregnant or become pregnant while participating in this study.

Possible advantages and disadvantages of your participation
You may not receive a direct benefit from your participation in this study. However, medical science and future test subjects can benefit from your participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* 18 years or older
* Abdominal pain consistent with choledocholithiasis
* Abnormal LFTs
* Non-complex biliary stone disease

Exclusion criteria

* Potentially vulnerable subjects, including but not limited to pregnant women and subjects in whom an endoscopic procedure is contraindicated.
* Location of the stones in intrahepatic ducts, cystic duct or proximal to strictures
* Bile duct stricture noted distal to stone on MRCP, which would make extraction without lithotripsy impossible.
* Ongoing cholangitis at time of randomization, manifested by fever with

tachycardia and hypotension or evidence of pus at the ampulla
* Patients with prior biliary sphincterotomy
* Patients with Primary Sclerosing Cholangitis (PSC)
* Acute pancreatitis
* Surgically altered gastro-duodenal luminal anatomy other than prior Billroth I Reconstruction
* Coagulopathy or ongoing need for anti-coagulation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	Cholangioscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-03-2020
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03421340
CCMO	NL67502.078.19