Cholangioscopy in intraductal staging of resectable extrahepatic CholangioCarcinoma

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To determine the technical feasibility of cholangioscopy using the Spyglass DS II system in the pre-operative work-up of resectable EC.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Observational invasive

Summary

ID

NL-OMON52099

Source
ToetsingOnline

Brief title
INSPECCT

Condition

- Gastrointestinal stenosis and obstruction
- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified

Synonym
bile duct cancer, cholangiocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cholangiocarcinoma, cholangioscopy, ERCP

Outcome measures

Primary outcome

Technical feasibility to perform cholangioscopy in EC, defined as the technical success to advance the Spyglass DS II cholangioscope through the malignant stricture into the intended (segmental) bile duct system(s), to assess ductal tumor borders optically and to obtain mapping biopsies of the locations of interest depending on the predetermined resection lines.

Secondary outcome

1. Overall diagnostic value of optical cholangioscopic assessment combined with biopsies of bile duct locations at interest outside the predetermined resection lines.

2. Diagnostic value of optical cholangioscopic assessment or biopsies alone.

3.Adverse outcomes after cholangioscopy defined by any cholangioscopy-related AE or mortality within 30 days. The AE will be recorded according the ASGE lexicon.

Study description

Background summary

Assessment of malignant bile duct extension is essential in pre-operative staging of extrahepatic, perihilar or distal, cholangiocarcinoma (EC). Current

diagnostic tests, including MRI/MRCP, are considered suboptimal in assessing longitudinal tumor growth. Cholangioscopy is a new endoscopic imaging technique performed during ERCP which provides direct visualization of the bile duct system, which also allows targeted biopsies.

Study objective

To determine the technical feasibility of cholangioscopy using the Spyglass DS II system in the pre-operative work-up of resectable EC.

Study design

Prospective pilot study in two referral centers.

Study burden and risks

Study related procedures will only be performed in patients already scheduled for ERCP. All patients have already consented for complications associated with an ERCP, including pain, hemorrhage, post-ERCP pancreatitis and perforation. Performing cholangioscopy during ERCP does not increase the risk of postprocedural complications. It will only prolong procedure time with an additional 20 minutes estimated. As patients are already sedated during ERCP adding cholangioscopy will not increase the burden of the endoscopic procedure. The presumed benefit of cholangioscopy is a change in pre-operative staging. In case finings of cholangioscopy incl biopsies differ from MRI/MRCP results, this will be discussed in the MDT. This may change management. Seldomly, cholangioscopy with biopsies demonstrate a benign bile duct disease instead of malignancy.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients with resectable EC undergoing ERCP to achieve pre-operative biliary decompression of the FRL
- (Suspicion of) EC is based on clinical assessment and imaging results (MRI/MRCP and CT), histological confirmation is not obligatory.
- Resectability of the tumor was evaluated at the regional multidisciplinary team meeting
- Biliary stenosis located distally, or perihilar according to Bismuth classification based on imaging results (MRI/MRCP/CT)
- Informed consent
- Age >= 18 years

Exclusion criteria

• Intrahepatic cholangiocarcinoma
• Irresectable tumor
• Previous treatment with a biliary plastic endoprothesis or self-expandable metal stent (SEMS)
• Previous treatment with a percutaneous transhepatic biliary drain
• Patients with expected very limited survival (< 6 weeks)
• Biliary obstruction not amenable to endoscopic drainage, for example due to altered anatomy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2023
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Spyglass DS II cholangioscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-06-2022
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL75313.041.21