Multimodality Preoperative Evaluation of lymph nodes of perihilar cholangiocarcinoma - a pilot study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON49893

Source
ToetsingOnline

Brief title
POELH

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
extrahepatic bile duct cancer, Perihilar cholangiocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Maag-, Darm- en Leverziekten
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endo-ultrasonography, Lymph nodes, Perihilar cholangiocarcinoma

Outcome measures

Primary outcome

- To evaluate the feasibility of systematic survey of regional and non-regional lymph nodes by EUS-FNA/FNB, defined as:

o Number of patients in which all potential lymph node locations were successfully surveyed and FNA/FNB is possible when indicated.

Secondary outcome

- To correlate regional and non-regional lymph nodes identified by EUS to cross-sectional imaging and surgery, defined as:

o Number of lymph nodes correctly identified as malignant based on visualization and biopsy in comparison to cross-sectional imaging and surgery

- To evaluate the different locations of positive lymph nodes and its effect on survival, defined as:

o Days of survival after EUS and surgery per N0, N1, N2 or M status.

- To identify short term and long term complications of EUS-FNA/FNB in detecting lymph nodes in patients with pCCA, defined as:

o Short term (<30 days)

* Sedation related: consisting of cardiovascular-related complications (cardiac arrhythmias, myocardial ischemia/infarction), respiratory- related complications (respiratory depression, hypoxia, airway obstruction, pulmonary aspiration of gastric contents) and allergic reactions.

* Hemorrhage (outside peritoneal wall): defined as clinical evidence of

bleeding with a hemoglobin drop of >3g/dl with the need for resuscitation or additional intervention

* Perforation: defined as evidence of air or luminal contents outside the gastro-intestinal tract together with clinical symptoms, requiring percutaneous drainage or surgery

* Mortality

o Long term (>30 days)

* Tumor seeding; defined as proof of carcinoma in the biopsy tract during follow-up or at autopsy

Study description

Background summary

The survival of patients with perihilar cholangiocarcinoma (CCA) is limited, as pCCA is often recognized in a relatively late stadium, making it ineligible for surgical resection, which is the only potentially curative treatment. The resectability of pCCA depends on local tumor extension, vascular involvement and presence of metastatic disease. Both distant and lymph node metastases are determining the choice of treatment and the prognosis, since the prognosis of patients with N2 lymph nodes or distant metastases is not altered by loco-regional surgery, and therefore surgical resection is contraindicated. Moreover, survival for patients with positive N1 lymph nodes is very poor and the small oncological advantage may not justify the surgical risk in some of these patients. Therefore, correct lymph node assessment is crucial, which is often difficult to determine preoperatively with cross-sectional imaging. Endoscopic Ultrasound (EUS) with Fine Needle Aspiration (FNA) or Fine Needle Biopsy (FNB) of the lymph nodes might be a more accurate method to assess lymph node staging, which might lead to a better preoperative shared decision making, since patients might be spared from invasive surgical treatments. Therefore, the aim of this pilot study is to evaluate the feasibility of systematic survey by EUS-FNA/FNB. In addition, the accuracy of lymph node assessment with EUS-FNA/FNB and its impact on clinical decision making will be compared to current state-of-the-art cross-sectional imaging (CT scan and Pet-MRI) and complications of EUS-FNA/FNB will be evaluated.

Study objective

The primairy aim of this pilot study is to evaluate the feasibility of systematic survey by EUS-FNA/FNB.

Study design

In preparation of a prospective multi-centered study, we aim to perform a pilot study at Erasmus MC, including 10 patients. The expected inclusion period is 6 months.

Intervention

In each patient with suspected resectable pCCA a systematic survey of regional and non-regional lymph nodes will be performed on cross sectional imaging, on EUS (with FNA or FNB of suspicious lymph nodes if present) and, when performed, during surgery.

Study burden and risks

In all patients with presumed resectable pCCA cross sectional imaging is performed. EUS is performed as standard if suspicious lymph nodes are present on imaging, but systematic survey of and reporting on the lymph nodes is not done. In patients without suspicious lymph nodes an additional EUS is performed, but with low risks. Due to systematic survey of the lymph nodes in all patients, a better estimate can be made about which patients benefit from the invasive curative-intent surgery and which patients do not because of the presence of positive lymph nodes. So, the benefit of this study is to spare patients from invasive surgery by identifying positive non-regional lymph nodes with EUS-FNA/FNB.

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

- Presumed resectable pCCA.
- Written informed consent must be given according to ICH/GCP, and national/local regulations.
- Age > 18 years.

Exclusion criteria

- Patients with a history of treated pCCA
- Patients with a history of treated liver malignancy
- Patients with a contra-indication for EUS + FNA/FNB (f.e. uncorrectable coagulopathy or platelet disorder), in line with current clinical practice

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2021
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	19-10-2021
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
CCMO	NL78298.078.21