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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26687

Source
NTR

Brief title
POELH

Health condition

Perihilar cholangiocarcinoma

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

- To evaluate the accuracy of EUS-FNA/FNB in regional and non-regional lymph nodes, compared to cross-sectional imaging and surgery, defined as:

o Number of lymph nodes correctly identified by EUS-FNA-FNB in comparison to surgery

Secondary outcome

- To evaluate the impact of EUS-FNA/FNB of both regional and non-regional lymph nodes on clinical decision making in patients with presumed resectable pCCA, defined as:
o Number of patients in whom surgery is withheld due to positive lymph nodes detected with EUS-FNA/FNB
- To evaluate the number of patients with positive lymph nodes detected with CT and Pet-MRI compared to EUS-FNA/FNB and to surgery when performed, defined as:
o Number of lymph nodes correctly identified by CT and Pet-MRI in comparison to EUS-FNA/FNB or 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 whether EUS with FNA or FNB of the lymph nodes (EUS-FNA/FNB) has added value for proper diagnosis of lymph node metastases in patients with presumed resectable pCCA and to evaluate its effect on clinical decision-making. 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

EUS-FNA/FNB can more accurately detect regional and non-regional lymph node metastasis than cross-sectional imaging and has a significant impact on clinical decision making.

Study design

Before EUS (imaging), EUS procedure and surgery (if performed)

Intervention

EUS, conform current clinical practice, to assess all lymph nodes through a systematic survey. FNA or FNB will be performed in any lymph node that is indicated suspicious.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all three following criteria:
• Presumed resectable pCCA.
• Written informed consent must be given according to ICH/GCP, and national/local regulations.
• Age > 18 years.

Exclusion criteria

A patient who meets any of the following criteria will be excluded from participation in this study:
• Patients with a history of treated pCCA
• Patients with a history of treated liver malignancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-07-2021
Application type:	First submission

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
NTR-new	NL9599
Other	METC EMC : MEC-2021-0519

Study results