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

Gepubliceerd: 05-07-2021 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26687

Bron
NTR

Verkorte titel
POELH

Aandoening

Perihilar cholangiocarcinoma

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2021
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9599
Ander register	METC EMC : MEC-2021-0519

Resultaten