

Titre	Diagnostic Value of Diffusion-weighted Magnetic Resonance Imaging for Detection of Peritoneal Metastases in High-risk Pancreatic Ductal Adenocarcinoma: a Pilot Study.
Protocole ID	2022-6186
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT05340569">NCT05340569</a>
Type(s) de cancer	Pancréas
Phase	Autres
Type étude	Diagnostic
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Statut	Actif en recrutement
Date d'activation	06-04-2022
But étude	<p>Diffusion-weighted magnetic resonance imaging (DWI/MRI) has been described in recent literature as a highly sensitive and specific modality for the detection of peritoneal metastases (PM). It has been demonstrated to be superior to computed tomography (CT) for patients with known peritoneal disease from colorectal and gynaecological malignancies. However, the literature is scarce on the role of DWI/MRI in patients with pancreatic ductal-adenocarcinoma (PDAC). The aim of this study is to prospectively assess the added value of whole-body DWI/MRI (WB-DWI/MRI) to CT for detection of PM in the preoperative staging of patients with high-risk PDAC and evaluate how it correlates with intraoperative findings. This is a prospective study from a single center. Patients will be evaluated and operated on by one of five surgeons with a subspecialty in hepato-biliary and pancreatic surgery. After thorough assessment for resectability, patients with PDAC considered resectable based on CT, but at high-risk for peritoneal disease, will be prospectively included in the study and assessed with WB-DWI/MRI within 4 weeks of the planned surgery, with the standard protocol including the following sequences: Patients will drink 1L of pineapple juice one hour prior to the examination in order to provide a negative intraluminal contrast. Patients will receive 20 mg of intravenous hyoscine butylbromide at the beginning of the MR exam in order to reduce bowel peristalsis. Sequences will include Axial et Coronal T2WI of the abdomen and pelvis, axial DWI with b values of 0, 50 and 1000 of the abdomen and pelvis, as well as Pre and post gadolinium-based contrast Axial and Coronal 3D T1WGRE. Patients with no evidence of PM on WB-DWI/MRI will be operated on and undergo pancreatic resection following the usual exploration of the peritoneal cavity in case of occult metastatic disease. Patients with suspicion of PM on WB-DWI/MRI will be approached with a diagnostic laparoscopy first, then undergo pancreatic resection if no evidence of PM is found. Each case will be followed for at least 6 months.</p>
Critères d'éligibilité	<ul style="list-style-type: none"> <li>Confirmed diagnosis of pancreatic ductal adenocarcinoma.</li> <li>Resectable disease or borderline resectable disease based on CT.</li> <li>Tumor size <math>\geq 3</math> cm.</li> <li>CA 19-9 <math>\geq 400</math> U/mL with normal bilirubin level (<math>&lt; 40</math>)</li> <li>No evidence of distant metastases.</li> <li>Patient fit for pancreatic resection (ECOG 0 or 1).</li> </ul>

#### Critères d'exclusion

- Impossibility to obtain tissue diagnosis preoperatively confirming pancreatic ductal adenocarcinoma.
- Locally advanced disease on CT.
- Tumor size < 3 cm.
- CA 19-9 < 400 U/mL or CA 19-9  $\geq$  400 U/mL with no preoperative drainage.
- Suspicion of distant metastases, including peritoneal metastases, on CT.
- Patient who is unable to have MRI.
- Patient unfit for pancreatic resection (ECOG 2 or more).