Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Traitement radionucléide par récepteur de peptide personnalisé de tumeurs neuroendocriniennes : étude de phase II
Protocole ID	A14-11-2181
ClinicalTrials.gov ID	NCT02754297
Type(s) de cancer	Tumeurs neuroendocrines
Phase	Phase II
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
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Statut	Actif en recrutement
But étude	In this study, peptide receptor radionuclide therapy (PRRT) with 177Lu-Octreotate (LuTate) will be personalized, i.e. administered activity of LuTate will be tailored for each patient to maximize absorbed radiation dose to tumor, while limiting that to healthy organsThe purpose of this study is to: • Assess the objective (radiological), symptomatic and biochemical response rates following an induction course of personalized PRRT; • Assess the overall, the disease-specific, and the progression-free survival following P-PRRT; • Correlate therapeutic response and survival with tumor absorbed radiation dose; • Evaluate the acute, subacute and chronic adverse events following P-PRRT; • Correlate toxicity (i.e. occurence and severity of adverse events) with absorbed radiation doses to organs at risk; • Optimize the quantitative SPECT imaging-based dosimetry methods in a subset of 20 patients (sub-study funded by the Canadian Institutes of Health Research). This study also has a compassionate purpose, which is to provide access to PRRT to patients.
Critères d'éligibilité	• Patient suffering from a progressive and/or symptomatic NET (any site); • Patient ineligible to, or refusing a potentially curative treatment such as surgical resection; • Patient who did not respond, is intolerant or refuses other indicated and available palliative treatments; • Demonstration of overexpression of somatostatin receptor by tumor lesions by scintigraphic imaging (Octreoscan or 68Ga positron emission tomography.
Critères d'exclusion	• Pregnancy; • Breastfeeding;. • Very limited survival prognosis (i.e. less than a few weeks, because of the NET disease or any other condition) or Eastern Cooperative Oncology Group (ECOG) 4 performance status; • Inability to obtain informed consent of the participant.