Essai Clinique

Généré le 19 avr. 2024 à partir de

Titre	Étude pivot, à répartition aléatoire et ouverte des champs de traitement de la tumeur (CTT, 150 kHz) concomitants avec la gemcitabine et le nab-paclitaxel pour le traitement de première intention de l'adénocarcinome pancréatique localement avancé
Protocole ID	PANOVA-3
ClinicalTrials.gov ID	NCT03377491
Type(s) de cancer	Pancréas
Phase	Phase III
Stade	Localement avancé
Type étude	Traitement
Médicament	Traitement des tumeurs par champs électriques (TTFields) combiné à la gemcitabine et au nab-paclitaxel
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Richard Létourneau
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Statut	Fermé
But étude	Cette étude a pour but principal de déterminer la survie globale du traitement de TTFields combiné à la gemcitabine et au nab-paclitaxel comparativement au traitement standard seul chez des patients atteints d'un cancer du pancréas localement avancé.
Critères d'éligibilité	• 18 years of age and older • Life expectancy of ≥ 3 months • Histological/cytological diagnosis of de novo adenocarcinoma of the pancreas • Unresectable, locally advanced stage disease according to the following criteria: • Head/uncinate process: • Solid tumor contact with SMA>180° • Solid tumor contact with the CA>180° • Solid tumor contact with the first jejunal SMA branch • Unreconstructible SMV/PV due to tumor involvement or occlusion (can be d/t tumor or bland thrombus) • Contact with most proximal draining jejunal branch into SMV • Body and tail • Solid tumor contact of >180° with the SMA or CA • Solid tumor contact with the CA and aortic involvement • Unreconstructible SMV/PV due to tumor involvement or occlusion (can be d/t tumor or bland thrombus) • No distant metastasis, including non-regional lymph node metastasis • No borderline resectable (per Al-Hawary MM, et al., Radiology 201414) • ECOG score 0-2 • Amenable and assigned by the investigator to receive therapy with gemcitabine and nab-paclitaxel • Able to operate the NovoTTF-100L(P) System independently or with the help of a caregiver • Signed informed consent form for the study protocol

Critères d'exclusion	• Prior palliative treatment (e.g. surgery, radiation) to the tumor • Cancer requiring anti-tumor treatment within the 5 years before inclusion, excluding treated stage I prostate cancer, in situ cervical or uterus cancer, in situ breast cancer and non-melanomatous skin cancer. • Serious co-morbidities: • Clinically significant (as determined by the investigator) hematological, hepatic and renal dysfunction, defined as: Neutrophil count < 1.5 x 10^9/L and platelet count < 100 x 10^9/L; bilirubin > 1.5 x Upper Limit of Normal (ULN); AST and/or ALT > 2.5 x ULN; and serum creatinine > 1.5 x ULN. • History of significant cardiovascular disease unless the disease is well controlled. Significant cardiac disease includes second/third degree heart block; significant ischemic heart disease; poorly controlled hypertension; congestive heart failure of the New York Heart Association (NYHA) Class II or worse (slight limitation of physical activity; comfortable at rest, but ordinary activity results in fatigue, palpitation or dyspnea). • History of arrhythmia that is symptomatic or requires treatment. Patients with atrial fibrillation or flutter controlled by medication are not excluded from participation in the trial. • History of cerebrovascular accident (CVA) within 6 months prior to randomization or that is not stable. • Active infection or serious underlying medical condition that would impair the ability of the patient to receive protocol therapy. • History of any psychiatric condition that might impair patient's ability to understand or comply with the requirements of the study or to provide consent. • Concurrent anti-tumor therapy beyond gemcitabine and nab-paclitaxel • Implantable electronic medical devices in the torso, such as pacemakers • Known severe hypersensitivities to medical adhesives or hydrogel, or to one of the chemotherapies used in this trial. • Pregnancy or breast-feeding (female patients with reproductive potential and their partners must accept to use effective contraception throughout the entire study period and for 3 months after the end of treatment). All patients who are capable of becoming pregnant must take a pregnancy test which is negative within 72 hours before beginning treatment. The definition of effective contraception is left up to the decision of the investigator. • Unable to follow the protocol for medical, psychological, familial, geographic or other reasons. • Admitted to an institution by administrative or court order.