Essai Clinique

Généré le 25 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	Tumor Treating Fields (TTFields) en combinaison avec gemcitabine et nab-paclitaxel
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
Investigateur principal	Dr Frédéric Lemay
Coordonnateur	Michelle Roy 819-346-1110 poste 12848
Statut	Fermé
But étude	The study is a prospective, randomized controlled phase III trial aimed to test the efficacy and safety of Tumor Treating Fields (TTFields) in combination with gemcitabine and nab-paclitaxel, for front line treatment of locally-advanced pancreatic adenocarcinoma.The device is an experimental, portable, battery operated device for chronic administration of alternating electric fields (termed TTFields or TTF) to the region of the malignant tumor, by means of surface, insulated electrode arrays.
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.