Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	LUNAR : Étude pivot ouverte à répartition aléatoire évaluant les champs de traitement des tumeurs (CTT) utilisés en concomitance avec les traitements standards dans les cas de cancer du poumon non à petites cellules (CPNPC) de stade 4 après l'échec d'un traitement par le platine
Protocole ID	EF-24
ClinicalTrials.gov ID	NCT02973789
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Tumor Treating Fields (TTFields)
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
Investigateur principal	Dre Nicole Bouchard
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Statut	Fermé
But étude	The study is a prospective, randomized controlled phase III trial aimed to test the efficacy and safety of TTFields, using the NovoTTF-100L System, concurrent with standard therapies for stage 4 NSCLC patients, following progression while on or after platinum based treatment.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	• 22 years of age and older • Life expectancy of ≥ 3 months • Histological diagnosis of squamous or non-squamous, inoperable, stage 4 NSCLC • Diagnosis of radiological progression while on or after first platinum-based systemic therapy • Randomization within 28 days of diagnosis of last progression • ECOG Score of 0-2 • Assigned by the physician to receive either docetaxel or immune checkpoint inhibitor per standard of care regimens • Able to operate the NovoTTF-100L device independently or with the help of a caregiver • Signed informed consent for the study protocol
Critères d'exclusion	• Presence of brain metastasis or leptomeningeal spread of the disease • Patients planned to receive immune checkpoint inhibitor with contra-indications to receive immunotherapy • Patients planned to receive docetaxel with contra-indications to receive docetaxel • Severe comorbidities: • 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 ULN; AST and/or ALT > 2.5 x ULN or > 5 x ULN if patient has documented liver metastases; 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 pericarditis
- History of interstitial lung disease
- 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 received 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
- Any other malignancy requiring anti-tumor treatment in the past three years, excluding treated stage I prostate cancer, in situ cervical cancer, in situ breast cancer and non-melanomatous skin cancer
- Concurrent treatment with other experimental treatments for NSCLC while on the study
- Implantable electronic medical devices (e.g. pacemaker, defibrillator) in the upper torso
- Known allergies to medical adhesives or hydrogel
- Pregnancy or breast-feeding (patients with reproductive potential must use effective contraception methods throughout the entire study period, as determined by their investigator/gynecologist)
- Admitted to an institution by administrative or court order