Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	Étude pivot randomisée en mode ouvert portant sur la radiochirurgie avec ou sans champs de traitement de la tumeur (ttfields) chez les patients porteurs de 1 à 10 métastases cérébrales consécutives à un cancer bronchopulmonaire non à petites cellules (CBNPC)
Protocole ID	Metis (EF-25)
ClinicalTrials.gov ID	NCT02831959
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr David Roberge
Coordonnateur	Diane Trudel 514-890-8000 poste 11181
Statut	Fermé
Date d'activation	04-07-2017
But étude	The study is a prospective, randomized controlled phase III trial, to test the efficacy, safety and neurocognitive outcomes of advanced NSCLC patients, following stereotactic radiosurgery (SRS) for 1-10 brain metastases, treated with NovoTTF-100M compared to supportive treatment alone. 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 • New diagnosis of brain metastases from a histologically or cytologically confirmed primary or metastatic NSCLC tumor within 5 years of registration on the study. If the original histological proof of malignancy is greater than 5 years, then pathological confirmation is required (i.e.: from extra-cranial or intracranial disease). • Karnofsky performance status (KPS) ≥ 70 • Graded Prognostic Assessment (GPA) score ≥ 2.0 • 1 inoperable brain metastasis or 2- 10 brain lesions per screening MRI, confirmed by contrast enhanced MRI amenable to SRS • At least one measurable lesion per RANO-BM (Response Assessment in Neuro-Oncology Brain Metastases) Criteria for brain metastasis • Patients must be receiving optimal therapy for their extracranial disease according to local practice at each center. Patients may continue on systemic therapy while receiving TTFields. • Able to operate the NovoTTF-100M device independently or with the help of a caregiver • Clinical trials prior to enrollment are allowed, as long as no brain directed therapy was included (current treatment trials are exclusionary)

Critères d'exclusion	• Patients who are known to have somatic tumor mutations in the following genes, for which targeted agents are available that directly affect the treatment of brain metastasis: Anaplastic lymphoma kinase (ALK), epidermal growth factor receptor (EGFR), ROS-1 proto-oncogene, and proto-oncogene B-RAF
	• Patients who have a single, operable brain metastasis
	• Patients with significant edema leading to risk of brain herniation
	• Patients with midline shift > 10mm
	• Patients with intractable seizures
	• Infratentorial metastases
	• Leptomeningeal metastases
	• Recurrent brain metastases or brain metastases previously treated with surgery and/or radiosurgery and/or brain radiotherapy
	• Prior surgical resection or WBRT for newly diagnosed brain metastases (needle biopsy for diagnosis establishment is allowed)
	• Severe comorbidities:
	  • Clinically-significant inadequate hematological, hepatic and renal function, 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); aspartate transaminase (AST) and/or alanine aminotransferase (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 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
	• Implantable electronic medical devices in the brain
	• Known allergies to medical adhesives or hydrogel
	• Currently pregnant or breastfeeding
	• Concurrent brain directed therapy (beyond SRS and NovoTTF-100M as per protocol)