Essai Clinique

Généré le 17 mai 2024 à partir de

Titre	A Prospective Multicenter Study of Transbronchial Microwave Ablation Using Robotic-Assisted Bronchoscopy in Subjects With Oligometastatic Tumors in the Lung
Protocole ID	POWER
ClinicalTrials.gov ID	NCT05299606
Type(s) de cancer	Autre
Phase	Autres
Type étude	Clinique
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Moishe Liberman
Coordonnateur	Adeline Jouquan 514-890-8000 poste 26214
Statut	Actif en recrutement
Date d'activation	09-01-2023
But étude	This is a prospective, multicenter, single-arm study on transbronchial microwave ablation using the NEUWAVE FLEX Microwave Ablation System and Accessories on oligometastatic tumors in the peripheral lung, guided by the Auris MONARCH Platform for visualization and access while using cone beam CT (computed tomography) to confirm probe tip placement and final ablation zone. The primary endpoint is Technique Efficacy, assessed 30-days post-ablation via CT imaging.
Critères d'éligibilité	• Signed informed consent. • Subjects greater or equal to 22 years old. • Performance status 0-2 (Eastern Cooperative Oncology Group classification (ECOG). • Willing to fulfill all follow-up visit requirements. • Subjects with at least one oligometastatic lung tumor where the primary tumor is controlled (in the opinion of the investigator or treating oncologist). • Oligometastatic lung tumor(s) planned to be ablated in the outer two-thirds of the lung and not closer than 1cm to the pleura.
Critères d'exclusion	• Pregnant or breastfeeding. • Subjects with thoracic implantable devices, including pacemakers or other electronic implants. • Chronic, continuous ventilator support, which uses bi-level positive airway pressure (PAP) to improve lung function for severe conditions. (However, intermittent PAP, for non-pulmonary conditions, such as sleep apnea, is permitted). • Prior pneumonectomy. • Severe bronchiectasis (with FEV1 <30%) or disease deemed to be too severe in the opinion of the investigator. • Platelet count ≤ 50,000/mm3. • Subjects with uncorrectable coagulopathy at time of screening. • Subjects medically unable to stop anti-platelet agents (e.g., aspirin, clopidogrel, prasugrel, ticagrelor) at least 5 days prior to the procedure through 48-72 hours after the procedure. • Subjects medically unable to stop warfarin at least 3-5 days prior to the ablation procedure, or until INR < 1.5, through 48-72 hours after the procedure. On the day of the procedure, subjects with an INR > 1.5 cannot have the procedure completed that day but may be rescheduled or postponed. • Subjects medically unable to stop anticoagulants (e.g., rivaroxaban, apixaban, dabigatran, endoxaban) at least 3 days prior to the ablation procedure through 48-72 hours after the

procedure.
- Expected survival less than 6 months in the opinion of the investigator and/or treating oncologist.
- Subjects with known or suspected brain metastases.
- Subject has had any radiation (i.e., SBRT or EBRT) to the intended ablation zone.
- Endobronchial tumors proximal to and including the segmental airways.
- Lung ablation, surgical resection therapy, radiotherapy, or any other treating procedure within 30 days prior to the planned study ablation procedure or those who plan to receive a lung ablation, surgical resection, or radiation therapy on the ablated lung side before completing the primary endpoint assessment (30 days post-ablation).
- Systemic therapy (e.g., chemotherapy, targeted drug therapy, or immunotherapy) within 14 days prior to the planned study ablation procedure or those who plan to receive systemic therapy before completing the primary endpoint assessment (30 days post-ablation).