Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	Étude randomisée de phase III comparant la résection lobaire partielle à une radiothérapie stéréotaxique chez les patients à haut risque ayant un cancer du poumon non à petites cellules de stade I.
Protocole ID	STABLE-MATES Trial (JoLT-Ca)
ClinicalTrials.gov ID	NCT02468024
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dre Édith Filion Dr Moishe Liberman
Coordonnateur	Adeline Jouquan 514-890-8000 poste 26214
Statut	Actif en recrutement
Date d'activation	05-02-2016
But étude	To Determine if SAbR improves survival over SR in High Risk Operable Stage I NSCLC
Critères d'éligibilité	• Age > 18 years. • ECOG performance status (PS) 0, 1, or 2. • Radiographic findings consistent with non-small cell lung cancer, including lesions with ground glass opacities with a solid component of 50% or greater. Those with ground glass opacities and <50% solid component will be excluded. • Biopsy confirmed non-small cell lung cancer. • Tumor ≤ 4 cm maximum diameter, including clinical stage IA and selected IB by PET/CT scan of the chest and upper abdomen performed within 60 days prior to registration. • All clinically suspicious mediastinal N1, N2, or N3 lymph nodes (> 1 cm short-axis dimension on CT scan and/or positive on PET scan) confirmed negative for involvement with NSCLC by one of the following methods: mediastinoscopy, anterior mediastinotomy EUS/EBUS guided needle aspiration, CT-guided, video-assisted thoracoscopic or open lymph node biopsy. • Tumor verified by a thoracic surgeon to be in a location that will permit sublobar resection. • Tumor located peripherally within the lung. NOTE: Peripheral is defined as not touching any surface within 2 cm of the proximal bronchial tree in all directions. See below. Patients with non-peripheral (central) tumors are NOT eligible. • No evidence of distant metastases. • Availability of pulmonary function tests (PFTs - spirometry, DLCO, +/- arterial blood gases) within 90 days prior to registration. Patients with tracheotomy, etc, who are physically unable to perform PFTs (and therefore cannot be tested for the Major criteria in 3.1.10 below) are potentially still eligible if a study credentialed thoracic surgeon documents that the patient's health characteristics would otherwise have been acceptable for eligibility as a high risk but nonetheless operable patient (in particular be eligible for sublobar resection). • Patient at high-risk for surgery by meeting a minimum of one major criteria or two minor criteria • No prior intra-thoracic radiation therapy. NOTE: Previous radiotherapy as part of treatment for head and neck, breast, or other non-thoracic cancer is permitted so long as possible radiation fields would not overlap. Previous chemotherapy or surgical resection specifically for the lung cancer being treated on this protocol is NOT permitted. No prior lung resection on the ipsilateral side. • Non-pregnant and non-lactating. Women of child-bearing potential must have a negative urine or serum pregnancy test within 60 days prior to registration. Peri-menopausal women must be amenorrheic > 12 months prior to registration to be considered not of childbearing potential.

	• No prior invasive malignancy, unless disease-free for ≥ 3 years prior to registration (exceptions: non-melanoma skin cancer, in-situ cancers). • Ability to understand and the willingness to sign a written informed consent.
Critères d'exclusion	• evidence of distant metastases • prior intra-thoracic radiation therapy. NOTE: Previous radiotherapy as part of treatment for head and neck, breast, or other non-thoracic cancer is permitted so long as possible radiation fields would not overlap. Previous chemotherapy or surgical resection specifically for the lung cancer being treated on this protocol is NOT permitted. No prior lung resection on the ipsilateral side. • pregnant and lactating women • prior invasive malignancy, unless disease-free for ≥ 3 years prior to registration (exceptions: non-melanoma skin cancer, in-situ cancers).