Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients With Osteosarcoma
Protocole ID	AOST2031
ClinicalTrials.gov ID	NCT05235165
Type(s) de cancer	Sarcome
Phase	Phase III
Type étude	Clinique
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL HOPITAL DE MONTREAL POUR ENFANTS 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dre Sharon Abish
Coordonnateur	Nawel Taghzouti 514-412-4400
Statut	Actif en recrutement
Date d'activation	29-12-2022
But étude	This phase III trial compares the effect of open thoracic surgery (thoracotomy) to thoracoscopic surgery (video-assisted thoracoscopic surgery or VATS) in treating patients with osteosarcoma that has spread to the lung (pulmonary metastases). Open thoracic surgery is a type of surgery done through a single larger incision (like a large cut) that goes between the ribs, opens up the chest, and removes the cancer. Thoracoscopy is a type of chest surgery where the doctor makes several small incisions and uses a small camera to help with removing the cancer. This trial is being done evaluate the two different surgery methods for patients with osteosarcoma that has spread to the lung to find out which is bette
Critères d'éligibilité	• Patients must be < 50 years at the time of enrollment. • Patient must have eligibility confirmed by rapid central imaging review. • Patients must have =< 4 nodules per lung consistent with or suspicious for metastases, with at least one of which being >= 3 mm and all of which must be =< 3 cm size. • Lung nodules must be considered resectable by either open thoracotomy or thoracoscopic surgery. Determination of resectability is made by the institutional surgeon. • Patients must have a histological diagnosis of osteosarcoma. • Patients must have evidence of metastatic lung disease at the time of initial diagnosis, or at time of 1st recurrence following completion of therapy for initially localized disease. • Patients with newly diagnosed disease must have completed successful gross tumor resection for their primary tumor or surgical local control of primary tumor must be planned to be performed simultaneously with thoracic surgery. • Newly diagnosed patients must be receiving systemic therapy considered by the treating physician as at least equivalent to methotrexate, doxorubicin and cisplatin (MAP) at the time of enrollment on this study. • Patients at time of 1st recurrence must have previously completed initial systemic therapy for their primary tumor, considered by the treating physician as at least equivalent to MAP.

Critères d'exclusion	• Patients with unresectable primary tumor. • Patients with pulmonary metastatic lesions that would require anatomic resection (lobectomy or pneumonectomy) or lesions that are defined as "central" (i.e., central lesion involves or is proximal to segmental bronchi and peripheral is lesion distal to segmental bronchi). • Patients with pleural or mediastinal based metastatic lesions, or with pleural effusion. • Patients with disease progression at either the primary or pulmonary metastatic site while on initial therapy. Note: Once the patient has been enrolled on the study, additional computed tomography (CT) scans are not anticipated prior to thoracic surgery. Note: Some variation in nodule size measurements over the course of pre-operative therapy is anticipated and does not qualify for exclusion unless deemed true disease progression by the primary treatment team. • Patients with evidence of extrapulmonary metastatic disease. • Patients who received pulmonary surgery for lung metastasis prior to enrollment. • All patients and/or their parents or legal guardians must sign a written informed consent. • All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met.