

Thoracotomy Versus Thoracoscopic Management of Pulmonary Metastases in Patients With Osteosarcoma

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: Up to 50 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Patients must be < 50 years at the time of enrollment.
- Patients must have $\leq$ 4 nodules per lung consistent with or suspicious for metastases, with at least one of which being $\geq$ 3 mm and all of which must be $\leq$ 3 cm size.
 - Note: Patient must have eligibility confirmed by rapid central imaging review.
- 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 or recently completed (within 60 days) systemic therapy considered by the treating physician to be standard treatment for newly diagnosed osteosarcoma (eg, cisplatin-doxorubicin or ifosfamide-based drug regimens) at the time of enrollment on this study. Dose and drug modifications for toxicity do not exclude patients from participation.
- Patients at time of 1st recurrence must have completed systemic therapy for their initial primary tumor, considered by the treating physician to be standard treatment for newly diagnosed osteosarcoma (eg, cisplatin-doxorubicin or ifosfamide-based drug regimens) at the time of enrollment on this study. Dose and drug modifications for toxicity do not exclude patients from participation.

Exclusion Criteria:

- 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 chest wall or mediastinal based metastatic lesions, or with significant 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 therapeutic 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.

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, OTHER: Questionnaire Administration, PROCEDURE: Thoracoscopy, PROCEDURE: Thoracotomy

Conditions:

Metastatic Malignant Neoplasm in the Lung, Metastatic Osteosarcoma, Osteosarcoma

More Information

Description:

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 better.

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Principal Investigator:

Principal Investigator ID:

Phase: PHASE3
IRB Number:
System ID: NCT05235165

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