

Testing Short-Course Radiation Versus Standard-Course Radiation for Soft Tissue Sarcomas That Need Surgery and Radiation

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have histological evidence of a soft tissue sarcoma from core or incisional biopsy. Participants must have a primary or locally recurrent tumor. Stage II-IIIb (by American Joint Committee on Cancer \[AJCC\] 8th edition) soft tissue sarcoma is required * Prior partial excision or partial excisional biopsy of the tumor, with imaging evidence of gross residual disease ≥ 1 cm in longest dimension (stage II-IIIb) * Participants must have a primary site of disease in the extremity, including the shoulder girdle and hip girdle but excluding the hands and feet * Participants with primary sites of trunk, head, neck, or intra-abdominal, intrapelvic, or retroperitoneal region are not eligible * Participants with extension of the primary tumor into adjacent regions (e.g. torso, hands, feet) are eligible * Participants must have an MRI of the primary site within 90 days prior to randomization. The MRI field of view must contain the entirety of the tumor (may be accomplished with multiple MRI scans). MRI must contain axial acquired T1 weighted with fat suppression, T1 weighted sequence with gadolinium contrast with fat suppression, and T2 weighted fat suppression sequence * Participants must have no evidence of metastatic disease by CT imaging of the chest (or positron emission tomography \[PET\] CT), within 28 days before randomization * Given the lack of specificity of chest CT, pulmonary nodule(s) ≤ 5 mm without a histological diagnosis are not exclusionary * Participants with pulmonary nodule(s) measuring 6-10 mm on chest CT are eligible if the nodules appear stable compared to prior chest imaging from at least 6 months ago, or if an fludeoxyglucose F-18 (18FDG)-PET scan indicates that the nodules are unlikely to be metastatic disease * Pulmonary nodules ≥ 10 mm should be considered metastatic unless proven otherwise by biopsy/resection or stable appearance for at least 6 months on imaging * Participants must not have fungating tumor. (i.e., tumor breakthrough of skin) * Participants must not have myxoid liposarcoma, embryonal rhabdomyosarcoma, alveolar rhabdomyosarcoma, gastrointestinal stromal tumor, osteosarcoma, neurotrophic tyrosine receptor kinase (NTRK)-rearranged spindle cell neoplasm, desmoplastic small round cell tumor, Ewing sarcoma, or sarcoma arising from bone * Participants must not have known brain metastases. Brain imaging studies are not required for eligibility if the participant has no neurologic signs or symptoms suggestive of brain metastasis. If brain imaging studies are performed, they must be negative for disease * Participants must have been evaluated by a surgeon, and it must have been determined that they are a good candidate for a limb salvage resection with an expectation of negative margins, within 35 days prior to randomization. Anticipated positive margins on fixed critical structures are allowed * Participants must not have had prior treatment for the current tumor (systemic therapy, radiation, or complete surgical resection) * Participants must not have had prior radiation to the anatomical site * Participants must be ≥ 18 years old at the time of randomization * Participants must have Zubrod performance status of 0-2 * Participants must have medical history and physical exam within 28 days prior to randomization. History and physical examination must include a description of the location of the tumor, including lateralization and extremity * Participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the investigational regimen * Participants must not be pregnant or nursing (nursing includes breast milk fed to an infant by any means, including from the breast, milk expressed by hand, or pumped). Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen * Participants must not have uncontrolled intercurrent illnesses or any other significant condition(s) that would make this protocol unreasonably hazardous * Participants with a history human immunodeficiency virus (HIV)-infection must be on effective anti-retroviral therapy at registration and have undetectable viral load test on the most recent test results obtained within 6 months prior to registration * Participants registered by sites located in the United States only must be offered the opportunity to participate in specimen banking * NOTE: As a part of the OPEN registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines * For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and Central Institutional Review Board (CIRB) regulations

Conditions & Interventions

Interventions:

RADIATION: 3-Dimensional Conformal Radiation Therapy, RADIATION: 3-Dimensional Conformal Radiation Therapy, PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, RADIATION: Intensity-Modulated Radiation Therapy, RADIATION: Intensity-Modulated Radiation Therapy, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Surgical Procedure

Conditions:

Recurrent Soft Tissue Sarcoma of the Trunk and Extremities, Resectable Soft Tissue Sarcoma of the Trunk and Extremities, Soft Tissue Sarcoma of the Trunk and Extremities, Stage II Soft Tissue Sarcoma of the Trunk and Extremities AJCC v8, Stage III Soft Tissue Sarcoma of the Trunk and Extremities AJCC v8

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

IRB

Number:

System ID: NCT07615049

Thank you for choosing StudyFinder. Please visit <http://studyfinder.cctr.vcu.edu> to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.