Phase II Multi-Institutional Study of Low-Dose (2Gy x 2) Palliative Radiotherapy in the Treatment of Symptomatic Bone metastases from Multiple Myeloma

Status: Recruiting

Eligibility Criteria

Sex: All
Age Group: 18 years and over

Inclusion Criteria:
Histologic diagnosis of multiple myeloma Painful bone metastasis (index lesion) that has a radiographic correlate Patient may have had any number of prior chemotherapy/immunotherapy regimens (changes to systemic therapy or use of bisphosphonates for 4 weeks before and after RT are allowed, but recording of these changes must be made so it can be accounted for) Eastern Cooperative Oncology Group (ECOG) 0-2 Brief Pain Inventory (BPI) score >= 2 Ability to understand and the willingness to sign a written informed consent

Exclusion Criteria:
Patients will be ineligible if the index lesion has received prior radiation therapy or prior palliative surgery. Patients may have received prior palliative or primary radiotherapy or surgery to other parts of the body, as long as the index lesion was not in the prior radiation fields and has not received prior palliative surgery Patients will also be ineligible if there is pathologic fracture or impending fracture at the site of the index lesion or planned surgical fixation of the bone at the index lesion Patients with clinical or radiographic evidence of spinal cord or cauda equina compression/effacement from the index lesion, and/or with index lesions located at the skull base or orbital lesions Patients must not be pregnant

Conditions & Interventions

Interventions:
Other: Quality-of-Life Assessment, Other: Questionnaire Administration, Radiation: Radiation Therapy

More Information

Description: This is a phase II prospective multi-institutional study. The main study objectives are: 1) To determine whether radiation treatment, with a total dose of 4 Gy, delivered over two days (2 fractions) to a painful myeloma bone lesion achieves patient-reported pain reduction comparable to historical controls at 4 weeks. 2) To assess quality of life in patients treated with 4Gy to painful myeloma bone lesions. 3) To quantify analgesia use/reduction following 4Gy to a painful myeloma bone lesion. All opioid analgesia use will be converted into morphine equivalent in order to compare across the entire population. 4) To measure time to pain relief and duration of pain relief with 4Gy. 5) To assess pain relief in patients with more than 1 index lesion.

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Phase: N/A
IRB Number: STUDY00010991

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