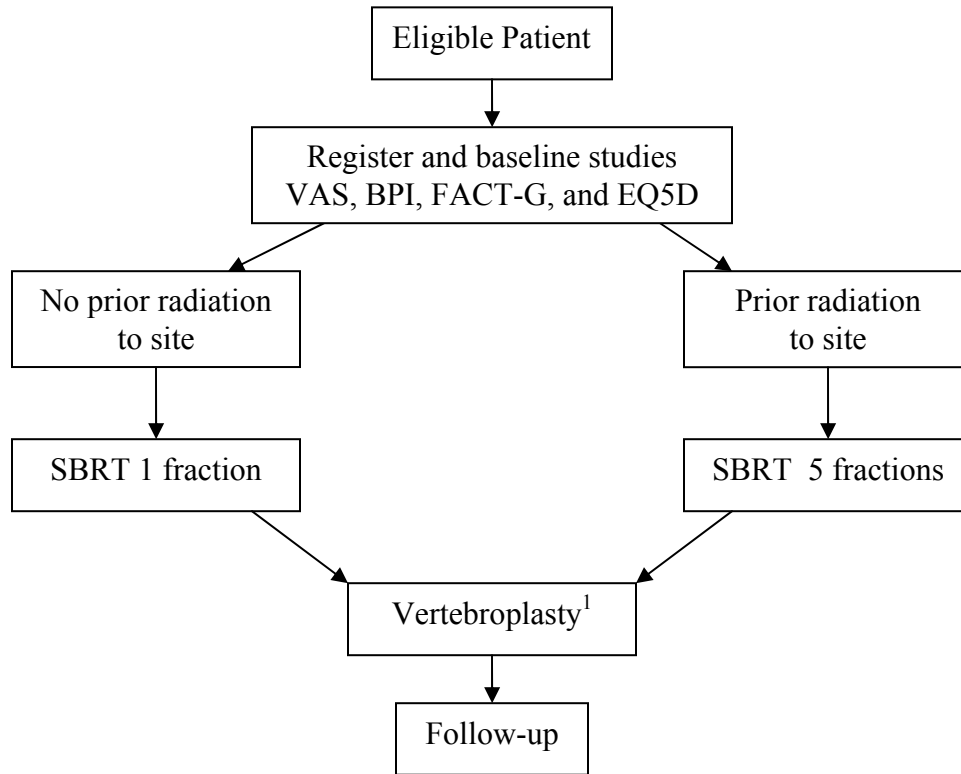


Title: Phase II Study of Stereotactic Body Radiation Therapy and Vertebroplasty for Localized Spinal Metastasis

Schema:



Number of patients: 29 patients for 1 fraction treatment having no prior radiation to the treatment site.
13 patients for 5 fraction treatment having a history of prior radiation to the treatment site.

Follow-up Assessment

- VAS² of treated spinal level at 2 weeks, 1, 3, and 6 months and then every 6 months for 3 years.
- Patient pain diary of maximum VAS of treated spine recorded once a week on the same day of radiation treatment for 5 weeks following radiation treatment.
- Clinical and neurological exams at 1, 3, 6, and then every 6 months for 3 years
- BPI, Fact-G, and EQ-5D at baseline, 1, 3, 6, and 12 months.
- MRI at baseline 1, 3, 6 and then every 6 months for 3 years.

Eligibility:

Inclusion:

- Patients must have localized spine metastasis (a solitary spine metastasis; two contiguous levels, or up to three separate single vertebral levels are permitted)
- Patients must have a VAS of ≥ 4 at any of the planned treatment sites

- Patient with epidural, spinal nerve, and/or cord compression on MRI may be included
- Histologic confirmation of cancer is required by biopsy, prior surgery, or re-biopsy
- Narcotic pain prescription and usage information must be available and documented
- Patients must sign study specific consent
- Above the age of 18
- For women of childbearing age a negative pregnancy test is required
- Patients considered for the retreatment arm, must not of had prior radiation to the proposed spinal site within a 3 month interval prior to treatment
- Zubrod score of 0-2

Exclusion:

- Patients who have been non-ambulatory for more than 7 days
- Patients with compression fractures
- Spine instability requiring fixation
- Patients with paraspinal extension
- Patients with bony fragments
- Planned systemic treatment within one week after treatment.
- Absence of pathological diagnosis of cancer
- Chemotherapy within one week of treatment
- Patients with Multiple Myeloma, Lymphoma, or Plasmacytoma
- Patient suffered from unstable angina and/or congestive heart failure requiring hospitalization within the last 6 months
- Patient had a transmural myocardial infarction within the last 6 months
- Patient has an acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration
- Patient has hepatic insufficiency resulting in clinical jaundice and/or coagulation defects
- PT is not within normal limits or planned and feasible to be corrected to normal limits prior to vertebroplasty
- PTT is not within normal limits or planned and feasible to be corrected to normal limits prior to vertebroplasty
- Platelet count is not within normal limits
- History of significant psychiatric illness

¹Vertebroplasty may not be possible for certain patients due to tumor location or safety. In such cases, patients will omit the vertebroplasty but receive all other protocol care and follow-up.

²Visual Analog Scoring