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| TITLE:  FACTORS INFLUENCING OUTCOMES AT THE END OF LIFE AMONG PATIENTS RECEIVING PALLIATIVE RADIATION THERAPY | | | | | |
| PRINCIPLE INVESTIGATOR(S): | | Monica Krishnan, MD | |  | SITE(S) (if applicable): |
| Dana Farber Cancer Center, Brigham and Women’s Hospital, DFCI at South Shore Hospital, BWH at Milford Regional Medical Center, and BWH/Sturdy Memorial radiation center |
| COORDINATING SITE: | | Dana Faber Cancer Center | |  |
| STUDY PERIOD | | | |  |
| START: | | January 1st, 2006 | |  |
| LAST SUBJECT CONTACT: | | No direct patient contact | |  |
| OBJECTIVES: | | | | | |
| **1. To examine factors influencing prognosis in patients receiving palliative radiation therapy, including validating the TEACHH model in a patient population receiving palliative radiation therapy at the DFCI and BWH, including the DFCI at South Shore Hospital, BWH at Milford Regional Medical Center and BWH/Sturdy Memorial radiation center, and examining other potential risk factors including laboratory values, burden of metastatic disease, changes in performance status, inpatient or outpatient status, specific symptoms, and treatment on a dedicated palliative care service and to determine their prognostic significance for survival.**  **2. To examine tumor/symptom control outcomes and toxicities after palliative radiation therapy over a patient’s remaining lifespan.** | | | | | |
| PARTICIPANTS | | | | | |
|  | ENROLLMENT | | ELIGIBILITY CRITERIA | | |
| Patients: | ~2,000 | | **Eligibility criteria are a diagnosis of an advanced, incurable cancer; age 18 years or older at the time of palliative radiation therapy; and treatment with palliative radiation therapy at Brigham & Women's Hospital or Dana-Farber Cancer Institute, including the DFCI at South Shore Hospital, BWH at Milford Regional Medical Center and BWH/Sturdy Memorial radiation center from January 1st, 2008 to 6 months prior to today’s date.** | | |
| Informal Caregivers: | 0 | | N/A | | |
| Health Care Providers: | 0 | | N/A | | |
| METHODOLOGY: | | | | | |
| **This is a retrospective record review which contains baseline disease information, radiographic information, clinical photographs, and follow-up information (including survival and resolution of symptoms). The associations between various baseline factors and outcomes, including life expectancy, tumor control, symptomatic improvement, will then be assessed.** | | | | | |
| INTERVENTION (if applicable): | | | | | |
| N/A | | | | | |
| MEASURES: | | | | | |
| **Demographic information, disease information (e.g., baseline and following the radiation therapy intervention), laboratory data (including LDH and WBC), performance status, systemic therapies, radiation therapy (initial treatment parameters and retreatment), treatment on a dedicated palliative care service, and symptoms, symptomatic improvement, and toxicities of treatment. Survival data, including date of death, to determine whether there is a correlation between the risk factors evaluated and time to death. As survival, toxicity and symptom improvement are three endpoints of our study, we required follow-up data and reviewed data from the charts through patients’ dates of death.** | | | | | |

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| BASELINE CHARACTERISTICS (TABLE 1) |

**PCRC STANDARDIZED DATA ELEMENTS**

***Please see the separate information sheet*** [***“DISC Standardized Data Elements”***](file:///C:\Users\csr26\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\JA16JP0K\Info%20Sheet%20-%20DISC%20Standardized%20Data%20Elements_v2018.08.docx) ***for the exact wording and format of the data elements.***

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| **DATA ELEMENT** | **Collected?** | **Var Name(s)** | **Data source (e.g. self-report, EHR) or reason not applicable** |
| 1. **Site ID (if multi-site)** |  |  |  |
| 1. **Who is the research participant? (e.g., patient, caregiver, etc.)** |  |  | All are patients |
| 1. **Sex** |  | Sex | Medical Record |
| 1. **Ethnicity** |  |  |
| 1. **Race** |  | Race | Medical Record |
| 1. **Age in years** |  |  |  |
| 1. **Current Marital Status** |  | Marital Status | Medical Record |
| 1. **Primary life-limiting diagnosis/illness** |  | Cancer Type | Medical Record |
| 1. **Performance status (AKPS)** |  | Karnosfsky | Medical Record |
| 1. **Enrolled in Hospice** |  |  |  |
| * 1. **If yes to hospice, where is hospice care provided?** |  |  |  |
| 1. **Receiving Palliative Care (PC)?** |  |  |
| * 1. **If yes to receiving PC, where is PC provided?** |  |  |  |
| 1. **Source of Death information** |  | Date of Death | Medical Record |
| 1. **Location of Death** |  |  |  |
| 1. **Enrolled in Hospice at time of death?** |  |  |  |
| 1. **Receiving PC at time of death?** |  |  |  |

***Cells in blue only need to be collected for patient research participants. Cells in orange should be collected regardless of participant type.***

**PATIENT REPORTED OUTCOME INSTRUMENTS**

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| **CONTENT**  *(e.g., PS)* | **ABBREV**  *(e.g., AKPS)* | **INSTRUMENT NAME**  *(e.g., Australian Modified Karnofsky Performance Status)* |
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