

Testing Longer Duration Radiation Therapy Versus the Usual Radiation Therapy in Patients With Cancer That Has Spread to the Brain

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Pathologically (histologically or cytologically) proven diagnosis of one of the following solid tumor malignancies within 5 years prior to registration: * Non-small cell lung cancer * Melanoma * Breast cancer * Renal cell carcinoma * Gastrointestinal cancer * If the original histologic proof of malignancy is greater than 5 years, then more recent pathologic confirmation (e.g., from a systemic site or brain metastasis) or unequivocal imaging confirmation of extracranial metastatic disease (e.g. CT of the chest/abdomen/pelvis, positron emission tomography \[PET\]/CT, etc.) is required * Patients must have at least 1 and up to 8 total intact brain metastases detected on a contrast-enhanced MRI performed ≤ 21 days prior to registration * At least 1 of the up to 8 lesions must be a study eligible lesion, defined as lesion with a maximum diameter as measured on any orthogonal plane (axial, sagittal, coronal) of ≥ 1.0 cm and ≤ 3.0 cm * All brain metastases must be located outside of the brainstem and ≥ 5 mm from the optic nerves or optic chiasm and ≤ 3.0 cm in maximum dimension * Note: brainstem metastases per the MRI within 21 days of registration are an exclusion criterion; however, if the MRI used for treatment planning performed within 7 days of SRS/FSRS reveals a brainstem metastasis, the patient remains eligible if the patient is considered an appropriate radiosurgery candidate per the local investigator * Patients must have a diagnosis-specific graded prognostic assessment ≥ 1.5 * No more than 2 lesions planned for resection if clinically indicated * No known leptomeningeal disease (LMD) * Note: For the purposes of exclusion, LMD is a clinical diagnosis, defined as positive cerebrospinal fluid (CSF) cytology and/or unequivocal radiologic or clinical evidence of leptomeningeal involvement. Patients with leptomeningeal symptoms in the setting of leptomeningeal enhancement by imaging (MRI) would be considered to have LMD even in the absence of positive CSF cytology. In contrast, an asymptomatic or minimally symptomatic patient with mild or nonspecific leptomeningeal enhancement (MRI) would not be considered to have LMD. In that patient, CSF sampling is not required to formally exclude LMD, but can be performed at the investigator's discretion based on level of clinical suspicion * Age ≥ 18 years * Karnofsky performance status (KPS) ≥ 60 * Negative urine or serum pregnancy test (in persons of childbearing potential) within 14 days prior to registration. Childbearing potential is defined as any person who has experienced menarche and who has not undergone surgical sterilization (hysterectomy or bilateral oophorectomy) or who is not postmenopausal * No prior radiotherapy to the brain (partial or whole brain irradiation, SRS, FSRS, or prophylactic cranial irradiation \[PCI\]) * New York Heart Association Functional Classification II or better (NYHA Functional Classification III/IV are not eligible) (Note: Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification) * No active infection currently requiring intravenous (IV) antibiotic management * No hepatic insufficiency resulting in clinical jaundice and/or coagulation defects * No chronic obstructive pulmonary disease exacerbation or other acute respiratory illness precluding study therapy

Conditions & Interventions

Interventions:

PROCEDURE: Computed Tomography, RADIATION: Fractionated Stereotactic Radiation Therapy, PROCEDURE: Magnetic Resonance Imaging, RADIATION: Stereotactic Radiosurgery

Conditions:

Anatomic Stage IV Breast Cancer AJCC v8, Metastatic Breast Carcinoma, Metastatic Digestive System Carcinoma, Metastatic Lung Non-Small Cell Carcinoma, Metastatic Malignant Neoplasm in the Brain, Metastatic Malignant Solid Neoplasm, Metastatic Melanoma, Metastatic Renal Cell Carcinoma, Stage IV Lung Cancer AJCC v8, Stage IV Renal Cell Cancer AJCC v8

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06500455

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