

Comparing the Addition of Radiation Either Before or After Surgery for Patients With Brain Metastases

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Radiographic confirmation of 1-4 brain metastases, one of which requires resection, as defined by magnetic resonance imaging (MRI) with contrast obtained within 14 days prior to registration * The maximum diameter of the lesion to be resected on the post-contrast MRI, as measured on any orthogonal plane (axial, sagittal, coronal), must measure ≥ 2.0 cm and ≤ 5.0 cm. * The maximum diameter of any lesions which will not be resected must be ≤ 4.0 cm in maximum diameter * Known active or history of invasive non-central nervous system (CNS) primary cancer based on documented pathologic diagnosis within the past 3 years * All brain metastases must be located ≥ 5 mm from the optic chiasm and outside the brainstem * Patient is able to medically tolerate surgery and SRS * Lesions chosen for surgical therapy must be deemed appropriate targets for safe, gross total resection by the treating surgeon * History/physical examination within 14 days prior to registration * Age ≥ 18 * Karnofsky performance status (KPS) ≥ 60 within 14 days prior to registration * A 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 * Participants who are sexually active must agree to use medically acceptable forms of contraception during treatment on this study to prevent pregnancy * The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the United States (U.S.), authorization permitting release of personal health information

Exclusion Criteria:

* Prior cranial radiotherapy, including whole brain radiotherapy, or SRS to the resection site * Note: The index lesion to be resected cannot have been previously treated with SRS (i.e. repeat radiosurgery to the same location/lesion is not allowed on this protocol). Previous SRS to other lesions is allowed * Evidence of 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 * Any medical conditions which would make this protocol unreasonably hazardous, including, but not limited to: contraindications to general endotracheal anesthesia; intracranial surgery; and stereotactic radiosurgery * Primary histology of germ cell tumor, small cell carcinoma or lymphoma * More than one brain metastasis planned for resection * Inability to undergo MRI with contrast * Planned administration of cytotoxic chemotherapy or tyrosine/multi-kinase inhibitors within the 3 days prior to, the day of, or within 3 days after the completion of SRS * Note: chemotherapy and immunotherapy outside of this window are allowed

Conditions & Interventions

Interventions:

PROCEDURE: Brain Surgery, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration, RADIATION: Stereotactic Radiosurgery

Conditions:

Metastatic Malignant Neoplasm in the Brain

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT05438212

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