Cancer Research Consortium of West Michigan
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FAST FACTS

ALLIANCE A071801 - PHASE III TRIAL OF POST-SURGICAL SINGLE FRACTION STEREOTACTIC RADIOSURGERY (SRS) COMPARED WITH FRACTIONATED SRS (FSRS) FOR RESECTED METASTATIC BRAIN DISEASE

Pre-Registration Eligibility Criteria

1. Non-CNS Primary Site
   Pathology from the resected brain metastasis must be consistent with a non-central nervous system primary site. Patients with or without active disease outside the nervous system are eligible (including patients with unknown primaries), as long as the pathology from the brain is consistent with a non-central nervous system primary site.
2. Number of Unresected Brain Metastases
   Three or fewer (i.e. 0 to 3) unresected brain metastases (as defined on the post-operative MRI) at the time of screening.
   Note: Dural based metastases (e.g. commonly seen in breast cancer) are eligible.
3. Size of Unresected Metastases
   Unresected lesions must measure <4.0 cm in maximal extent on the contrasted post-operative treatment MRI brain scan. The unresected lesions will be treated with SRS as outlined in the treatment section of the concept.
   Note: The metastases size restriction does not apply to the resected brain metastasis.
4. Number of Resected Brain Metastasis
   One brain metastasis must be completely (gross total resection) resected ≤30 days prior to pre-registration. For reference, please find Residual Disease Exclusion Cases on the A071801 study-specific webpage on the Alliance and CTSU websites.
   NOTE: May not have had resection of more than one brain metastasis
5. Size of Resected Brain Metastasis
   The resected brain metastasis must measure 2 cm or larger on the pre-operative scan. Note: MRI is preferred, but CT of the head with IV contrast is allowed for pre-operative imaging.
6. Size of Resection Cavity and Extent of Resection
   Resection cavity must measure <5.0 cm in maximal extent and the resection must be complete (gross total resection) on the post-operative MRI obtained ≤30 days prior to pre-registration.
7. Age ≥ 18 years
8. Karnofsky Performance Status of ≥60
9. For women of childbearing potential only, a negative urine or serum pregnancy test done ≤ 7 days prior to pre-registration is required
   - Men and women of childbearing potential must be willing to employ adequate contraception throughout the study and for men for up to 3 months after completing treatment.
   - A female of childbearing potential is a sexually mature female who: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturally postmenopausal for at least 12 consecutive months (i.e., has had menses at any time in the preceding 12 consecutive months).
10. Ability to complete an MRI of the head with contrast
11. The brain metastasis must be located >5mm of the optic chiasm; the brain metastasis must be located outside the brainstem (i.e. not inside the brainstem)
12. Must not have any prior whole brain radiation therapy.

13. Past radiosurgery to other lesions is allowed
    NOTE: The surgically resected lesion cannot be the same location treated in the past with radiosurgery (i.e. repeat radiosurgery to the same location/lesion is not allowed on this protocol)
14. May not have primary germ cell tumor, small cell carcinoma, or lymphoma.
15. No evidence of leptomeningeal metastasis (LMD).
    NOTE: For the purposes of exclusion, LMD is a clinical diagnosis, defined as positive CSF cytology and/or equivocal 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, unless a parenchymal lesion can adequately explain the neurologic symptoms and/or signs. 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 [47].
16. Must be fluent in English, Spanish, or French.

Registration Eligibility Criteria

1. Completion of all baseline ePRO (or booklet quality of life measures) and MoCA.

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