Doctor's Note — Clinical Trial Summary

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TRIAL

Stereotactic Radiosurgery and Immune Checkpoint Inhibitors With NovoTTF-200M for the Treatment of Melanoma Brain Metastases

NCT ID: NCT05341349 Phase: PHASE1 Sponsor: Emory University Status: Terminated

SUMMARY

This phase I trial finds out the side effects and possible benefits of stereotactic radiosurgery and immune checkpoint inhibitors with NovoTTF-100M for the treating of melanoma that has spread to the brain (brain metastases). Stereotactic radiosurgery is a type of external radiation therapy that uses special equipment to position the patient and precisely give a single large dose of radiation to a tumor. It is used to treat brain tumors and other brain disorders that cannot be treated by regular surgery. Immunotherapy with monoclonal antibodies, such as pembrolizumab, nivolumab and ipilimumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. NovoTTF-100M is a portable battery operated device which produces tumor treating fields in the body by means of surface electrodes placed on the skin. Tumor treating fields are low intensity, intermediate frequency electric fields that pulse through the skin to disrupt cancer cells' ability to divide. Giving stereotactic radiosurgery and immune checkpoint inhibitors with NovoTTF-100M may work better than stereotactic radiosurgery and immune checkpoint inhibitors.

KEY ELIGIBILITY CRITERIA

- * Be willing and able to provide written informed consent for the trial
- * Have diagnosis of malignant melanoma.
- * Be \>= 22 years of age on the day of signing informed consent
- * Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0-1 or Karnofsky performance status \>= 70%
- * Patients must have histological diagnosis of melanoma
- * Preference is for treatment naive patients that have not gotten previous immunotherapy. However, if approved by principal investigator (PI), patients that have gotten prior PD1 and/or dual immune checkpoint inhibitor therapy may be allowed on this trial if they have progressed intra-cranially or extra-cranially, and have very limited disease progression.
- * Patient must be asymptomatic at time of getting SRS (day 0) on trial. Prednisone =\< 20 mg/day (4 mg or less of dexamethasone equivalent) for at least 7 days prior to treatment is allowed
- * Patients with ocular, mucosal and unknown primary melanoma will also be eligible
- * Patients with 1-10 untreated brain metastases at time of initial brain metastases diagnosis (surgery to at least one of the brain lesions and/or biopsy of a lesion for diagnostic purposes and/or for standard of care purposes is acceptable). If patient has surgical removal of at least one lesion, the investigator would wait for a reasonable time after surgery to start the TTFields, SRS and Immunotherapy. This is typically around 2-4 weeks after resection and clearance by neurosurgery to start the treatment. However, the exact time to start would depend on institutional standard of care practice pattern. Enrollment of patient can take place before or after planned surgery.
- * Eligible for hypofractionation approach (9 Gy x 3 or 6 Gy x 5). 9 Gyx 3 is preferred approach, but 6 Gy x 5 fractions is acceptable

Total sites: 1 | 0 currently recruiting