

Immunotherapy for Recurrent Ependymomas in Children

Treatment for Recurrent Ependymomas using HLA-A2-restricted tumor antigen peptides in combination with imiquimod

Protocol Description

The purpose of this study is to determine whether vaccination with HLA-A2-restricted tumor antigen peptides combined with the immunoadjuvant imiquimod is safe and can induce immune responses in children with recurrent ependymomas. Patients will be stratified by primary tumor location.

Eligibility Criteria

Children between the ages of 12 months and 21 years who have been diagnosed with recurrent ependymoma. All grades of ependymomas are eligible.

Stratum A: Patients with recurrent ependymoma with the primary site in the posterior fossa. Patients may have nonbulky asymptomatic metastatic disease. Patients may have undergone surgical resection or debulking prior to enrollment.

Stratum B: Patients with recurrent ependymoma with the primary site outside the posterior fossa. Patients may have nonbulky asymptomatic metastatic disease. Patients may have undergone surgical resection or debulking prior to enrollment.

- HLA-A2 positive based on flow cytometry performed at the University of Pittsburgh.
- Patients must have previously received standard initial therapy, including attempted gross total resection, where safely feasible, and in appropriate circumstances (e.g., those older than 1 year at initial diagnosis, with nonmetastatic tumors and at least microscopic residual disease) involved field fractionated radiation therapy (RT).
- Patients may have received reirradiation but must be at least four weeks from the completion of RT.
- Patients must be clinically stable and off or on low dose (no more than 0.1 mg/kg/day, max 4 mg/day dexamethasone) corticosteroid for at least one week prior to study registration.
- Patients must be between ≥ 12 months and < 22 years of age at the time of screening.
- Patients must have a performance status of ≥ 70 ; (Karnofsky if ≥ 16 years and Lansky if < 16 years of age).
- Patients may have nonbulky asymptomatic disease.
- Patients must be free of systemic infection at the time of registration and off IV antibiotics for at least seven days prior to registration.
- Patients must have adequate organ function as measured by:
 - Bone marrow: ANC $> 1,000$ /ml; Platelets $> 100,000$ /ml (transfusion independent); absolute lymphocyte count of ≥ 500 /uL; Hemoglobin > 8 g/dl (may be transfused).
 - Hepatic: Bilirubin ≤ 1.5 x institutional normal for age; SGPT (ALT) < 3 x institutional normal.
 - Renal: Normal serum creatinine based on age or creatinine clearance or radioisotope GFR ≥ 70 ml/min/1.73 m².
- Patients must have recovered from the toxic effects of prior therapy and be at least three weeks from the last dose of standard cytotoxic chemotherapy or myelosuppressive biological therapy, and at least one week from the last dose of non-myelosuppressive biological therapy.
- Patients must have no overt cardiac, gastrointestinal, pulmonary, or psychiatric disease.

Requirements

Patients must be willing to travel to Pittsburgh for treatment. Physical exams to monitor side effects will be done at the time of each vaccine. Blood tests for immunologic monitoring and MRI scans to evaluate tumor status will be done every six to 12 weeks.

Visits: Every three weeks x 8, then every six weeks x 12 depending on response/side effects

Duration: Up to two years

Status: Open for Enrollment

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