UPMC | CHILDREN'S HOSPITAL OF PITTSBURGH

CLINICAL TRIAL

Phase 2 Immunotherapy Study for Recurrent Low-Grade Gliomas in Children

Treatment for Recurrent Low-Grade Gliomas using HLA-A2-restricted tumor antigen peptides in combination with poly-ICLC

Protocol Description

The purpose of this research study is to build upon the promising results of our pilot study for these tumors (*Neuro-Oncology* 18: 1157-1168, 2016) to determine the efficacy of vaccination with HLA-A2-restricted tumor antigen peptides combined with the immunoadjuvant poly-ICLC in children with recurrent low-grade gliomas.

Efficacy will be defined by imaging-based tumor response and progression-free survival, in parallel with assessments of immune response.

Eligibility Criteria

- Unresectable low-grade gliomas that have progressed after at least two chemotherapy or biologic regimens (radiation therapy counts as one biologic regimen). Patients must not have received radiation to the index lesion within one year of enrollment.
- HLA-A2 positive based on flow cytometry performed at the University of Pittsburgh.
- Patients must be between ≥ 12 months and < 22 years of age at the time of initial HLA screening.
- 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 have a performance status of ≥ 70; (Karnofsky if ≥ 16 years and Lansky if < 16 years of age).
- 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 ≤ 1.5x institutional normal for age; SGPT (ALT) < 3x institutional normal.
  - Renal: Normal serum creatinine based on age or creatinine clearance or radioisotope GFR ≥ 70 ml/min/1.73 m^2.
- Patients must have recovered from the toxic effects of prior therapy and be at least three weeks from the last dose of 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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