Visit ClinicalTrials.gov for a full description of the trial.

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ACTION Clinical Trial
A research study for pediatric patients with newly diagnosed high-grade gliomas, or HGG.

Fast Facts

ACTION is a Phase I clinical trial evaluating the safety of adoptive cellular therapy in pediatric patients with HGG receiving dose-intensified temozolomide, or TMZ, and dendritic cells, or DC, with autologous lymphocyte transfer (DC + xALT therapy) with and without hematopoietic stem cell, or HSC, infusion.

This study includes three distinct parts:
- Surgery
- Chemoradiation
- Adjuvant TMZ with immunotherapy

Up to 18 patients will be enrolled (to treat 12 evaluable) in the Phase I trial. All subjects will undergo surgical resection of tumor for disease debulking and preparation of tumor RNA.

Subjects will be grouped into cohorts that receive DC and xALT alone (Group A) or DC and xALT with HSCs (Group B).

Subjects will undergo mobilized leukapheresis for generation of DC vaccine (#1-3) and collection of peripheral blood stem cells, or PBSC. Following DC vaccine #3, subjects will undergo a second non-mobilized leukapheresis for production of DC vaccines (#4-10).

All subjects will receive chemoradiation, one cycle of dose-intensified TMZ, or DI-TMZ, biweekly DC vaccines, then four more cycles of DI-TMZ, with DC vaccines after each cycle. xALT infusion and DC vaccine will follow cycle 6 of DI-TMZ. DC vaccines #8-10 will be given 1 month after cycle 6. All subjects will be followed until death due to any cause.

Subject inclusion criteria
- Age: 3 to ≤ 21 years old, scheduled for definitive surgical resection of suspected HGG (biopsy-only subjects are not eligible for this study)
- Histopathologic diagnosis of WHO Grade III or IV malignant glioma
- Performance score > 60 (Lansky or Karnofsky)
- Adequate organ performance suitable for chemoradiation and DI-TMZ

Subject exclusion criteria
- Residual post-surgical disease burden > 3 cm
- Midline unresectable tumors
- Known immunosuppressive disease