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A phase I/II clinical trial investigating the adverse and therapeutic effects of a postoperative autologous dendritic cell tumor vaccine in patients with malignant glioma.

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Abstract

Previous clinical trials of dendritic cell (DC)-based immunotherapy in patients with glioblastoma multiforme (GBM) have reported induction of systemic immune responses and prolonged survival. From 2003 to 2005, we performed a clinical trial in which patients with malignant glioma underwent surgery for maximal cytoreduction followed by a 6-month 10-injection course of autologous DC-tumor vaccine therapy, each injection containing $1-6 \times 10^7$ DC. Of the 17 treated patients (16 with World Health Organization grade IV and one with grade III glioma), eight (47.1%) had an initial transient elevation in aspartate aminotransferase (AST)/alanine aminotransferase (ALT). Vaccination caused some tumor shrinkage and increased concentration of tumor-infiltrating CD8(+) lymphocytes. Median survival and 5-year survival were 525days and 18.8%, respectively, for 16 patients with grade IV glioma (381days and 12.5% for eight newly diagnosed; 966days and 25% for eight relapsed patients) compared to 380days and 0% for 63 historical control patients. We concluded that autologous DC-tumor immunotherapy benefits patients with malignant glioma but may cause transient but reversible elevation of serum AST/ALT levels.

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