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[J Neurosurg.](#) 2011 May 13. [Epub ahead of print]

Phase I/IIa trial of autologous formalin-fixed tumor vaccine concomitant with fractionated radiotherapy for newly diagnosed glioblastoma.

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Abstract

Object The objective of the present study was analysis of results of the prospective clinical trial directed toward the evaluation of therapeutic efficacy of the administration of autologous formalin-fixed tumor vaccine (AFTV) concomitant with fractionated radiotherapy in cases of newly diagnosed glioblastoma multiforme. **Methods** Twenty-four patients were enrolled into the clinical trial, while 2 cases were excluded from the final analysis of results. The treatment protocol included aggressive tumor resection, fractionated radiotherapy up to a total dose of 60 Gy, and 3 concomitant courses of AFTV administered with an interval of one week at the late stage of irradiation. Two delayed-type hypersensitivity (DTH) tests were done—one 48 hours before the initial course of vaccination (DTH-1) and one 2 weeks after the third (DTH-2). All but one of the patients received salvage therapy at the time of tumor progression. The defined primary end point was overall survival; secondary end points were progression-free survival and safety of concomitant treatment. **Results** The median duration of overall survival was 21.4 months (95% CI 13.8-31.3 months). The actuarial 2-year survival rate was 40%. The median duration of progression-free survival was 7.6 months (95% CI 4.3-13.6 months). Overall survival showed a statistically significant association with recursive partitioning analysis class ($p < 0.05$); progression-free survival showed a statistically significant association with p53 staining index ($p < 0.05$) and size of DTH-2 response ($p < 0.001$). AFTV injection concomitant with fractionated radiotherapy was well tolerated by all patients and in no case did treatment-related adverse effects exceed Grade 1 toxicity; adverse effects were limited to local erythema, induration, and swelling at the site of injection. **Conclusions** The results of this study demonstrate that AFTV treatment concomitant with fractionated radiotherapy may be effective in patients with newly diagnosed glioblastoma. Further clinical testing is warranted.

PMID: 21568657 [PubMed - as supplied by publisher]

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