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Phase I Trial of a Personalized Peptide Vaccine for Patients Positive for Human Leukocyte Antigen-A24 With Recurrent or Progressive Glioblastoma Multiforme.

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Abstract

PURPOSE Personalized selection of suitable peptides for patients could offer a novel approach to developing cancer vaccines that boost anticancer immunity. We present the results of a phase I trial of 14 kinds of vaccine candidates (ITK-1) in patients with recurrent or progressive glioblastoma multiforme (GBM). **PATIENTS AND METHODS** From January 2006 to January 2008, 12 patients from eight Japanese hospitals who were positive for human leukocyte antigen-A24, including 10 patients refractory to temozolomide (TMZ), were enrolled. The dose escalation trial included three dose groups (1, 3, and 5 mg) to determine the safety and tolerability of ITK-1 peptides. Immunologic response was monitored by measuring levels of cytotoxic T-lymphocyte precursors and peptide-specific immunoglobulin G. In another ITK-1 phase I trial for advanced prostate cancer, the vaccination schedule was skipped or discontinued in all three patients receiving the highest dose (5 mg/peptide) because of injection site reactions. This trial was therefore ended without enrollment for the highest dose, and data were analyzed by intention to treat. **Results** No serious adverse drug reactions were encountered, and treatment was well tolerated. The vaccine induced dose-dependent immune boosting. The recommended dose of ITK-1 peptides is 3 mg/peptide. **CONCLUSION** Personalized vaccination with ITK-1 peptides could be recommended in further stages of clinical trials. The safety and increased frequency of immune boosting offers potential clinical benefits in cases of recurrent or progressive GBM, even in TMZ-refractory settings.

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