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Vaccination of prostate cancer patients with a therapeutic vaccine containing prostate specific antigen (PSA) and the biological adjuvant IL-2 and GM-CSF results in reduced serum PSA

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Abstract

In 1997 we initiated a phase I/II clinical trial of a therapeutic prostate cancer vaccine. We have enrolled 12 biopsy confirmed prostate cancer patients in this study and 11 finished the initial course of 6 intradermal vaccinations containing prostate specific antigen (50 µg) and biological adjuvants (IL-2, 20,000 units, and GM-CSF, 16.7 µg) at 0, 1, 2, 6, 10 and 14 weeks. During this study the prostate cancer patients received no other concurrent therapy (surgery, hormone, radiation, radioactive seeds, chemotherapy). One of the 12 patient's PSA rose from 7.6 to 13.7 after the fourth vaccination and he (patient #8) withdrew from the study to seek other therapy. In the remaining 11 prostate cancer patients serum PSA concentrations were determined before initiating vaccination and 3-4 weeks after the 6th vaccination. There was a decrease in the PSA levels in 8 of 12 of the prostate cancer patients after 6 vaccinations. One of the patients (patient #3), whose PSA had dropped from 6.8 to 6.4 and had previously received radiotherapy (the only patient previously treated), elected to withdraw from the study and underwent radical prostatectomy. Nine of the original 12 patients have received monthly 3 intradermal IL-2 injections (11 million units) alternated with 3 further vaccinations for the 6 months following the initial vaccinations, and 8 patients have been followed from 18 to 92 months. The mean PSA values for the 8 patients still being followed without additional therapy were 5.8 initially, decreasing to 4.1 after 6 vaccines, 3.7 after 12 vaccines and is 4.7 after a mean follow-up of 49 months (median follow-up of 45.5 months). These promising results have led to the creation of the U.S. Navy Cancer Vaccine Program with a Phase I clinical trial at the Veterans Administration Medical Center San Diego/UCSD Medical School.