

Vaccine approach extends life of metastatic prostate cancer patients

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In a newly published clinical trial, patients with metastatic prostate cancer who received a vaccine of harmless poxviruses engineered to spur an immune system attack on prostate tumor cells lived substantially longer than patients who received a placebo vaccine, report researchers at Dana-Farber Cancer Institute and affiliated organizations. The findings will be published by the *Journal of Clinical Oncology* on its Web site and later in a print edition.

The randomized phase II study involved the PROSTVAC-VF vaccine, a combination of two weakened poxviruses that have been genetically programmed to produce slightly irregular versions of prostate specific antigen (PSA) - a protein on the surface of prostate cells that is abnormal in many prostate cancers - and three costimulatory molecules that spur the immune system to a more vigorous attack on tumor cells. The double-blinded trial included 125 patients with metastatic prostate cancer who did not respond to standard, hormone-lowering therapy. Eighty-two of the participants received the vaccine, produced by BN ImmunoTherapeutics, Inc., of Mountain View, Cal., and 40 received a placebo.

At the three-year point after the study, 30 percent of the PROSTVAC-VF patients were alive, versus 17 percent of the control group. The median survival of the vaccine group was 24.5 months, compared to 16 months for the control group, an 8.5-month increase. Patients tolerated the vaccine well; only a small number experienced side effects such as fatigue, fevers, and nausea.



"Although this study is relatively small, it offers encouraging evidence of a clinically meaningful benefit from this <u>vaccine</u> approach," says principal investigator and lead author Philip Kantoff, MD, of Dana-Farber, who helped design the trial. Investigators are planning a phase III trial that will enroll about 600 patients to further evaluate the vaccine's effectiveness.

Provided by Dana-Farber Cancer Institute

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