

Medical News

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CANCER VACCINE SHOWS BENEFIT IN EARLY HUMAN CLINICAL TRIAL

COLUMBUS, Ohio – A novel cancer vaccine developed by researchers at the Ohio State University Comprehensive Cancer Center-James Cancer Hospital and Solove Research Institute has shown evidence of being effective, as well as safe, in a phase I clinical trial involving both men and women and a variety of cancer types.

The vaccine targets a protein called HER-2, which is present at abnormally high levels in about one-third of breast cancers and in other cancer types. Its presence generally signals a poor response to therapy and a high likelihood that a cancer will recur.

Twenty-four men and women with metastatic or recurrent solid tumors participated in the trial.

The [findings](#) were reported recently in the Journal of Clinical Oncology.

“Of the 24 patients, six showed clinical benefit – one had tumor shrinkage and five had stable disease,” says principal investigator and study leader Pravin T. P. Kaumaya, professor of obstetrics and gynecology, of molecular and cellular biochemistry, and of microbiology, and director of the division of vaccine development.

“Our findings strongly suggest that this vaccine should be tested for clinical efficacy in a phase II trial,” Kaumaya says.

While most HER-2 vaccines in clinical trial generate a killer T-cell immune response against cancer cells expressing the protein, the Ohio State University vaccine generates an antibody immune response by the body against the protein, Kaumaya says. That is, it works similar to the synthetic antibody-based drug Herceptin, but because the vaccines stimulate the body’s own antibodies against the tumor, it avoids the cardiac, gastrointestinal and other serious side effects associated with the drug.

The antibodies produced by the vaccine also target two different regions of the HER-2 protein, enabling the vaccine to suppress both the activation of the protein in cancer cells and the proliferation of cancer cells.

Patients participating in the trial had cancers that included breast, ovarian, colon, uterine and cervical. Only some of the tumors were HER-2 positive, and only one of the six patients showing clinical benefit was HER-2 positive; the others did not overexpress the protein.

“This led to the unexpected finding that the vaccine might benefit 60 percent of all cancer patients with solid tumors, and more importantly those that overexpress the epithelial growth-factor receptor,” Kaumaya says. The epithelial growth-factor receptor (EGFR) is a receptor protein that partners with HER-2 in cells (in fact, it’s named HER-1). It is often present at abnormally high levels in lung, colon and other cancers.

Finally, the trial showed that even the highest of the four vaccine doses used in the trial caused few side effects.

New data related to the vaccine's molecular structure has enabled Kaumaya and his colleagues to produce an improved, second-generation version, and the National Cancer Institute has provided funding for a new phase I trial to test the improved vaccine in humans. That trial is set to begin in July 2010 and will target breast, ovarian, lung, colon, pancreatic and gastrointestinal stromal tumors (GIST).

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Other Ohio State researchers involved in this study were Kevin Chu Foy, Joan Garrett, Sharad V. Rawale, Daniele Vicari, Jennifer M. Thurmond, Tammy Lamb, Aruna Mani, Yahaira Kane, Catherine R. Balint, Donald Chalupa, Gregory A. Otterson, Charles L. Shapiro, Jeffrey M. Fowler, Michael R. Grever, Tanios S. Bekaii-Saab and William E. Carson III.

The Ohio State University Comprehensive Cancer Center- Arthur G. James Cancer Hospital and Richard J. Solove Research Institute is one of only 40 Comprehensive Cancer Centers in the United States designated by the National Cancer Institute. Ranked by U.S. News & World Report among the top 20 cancer hospitals in the nation, The James (www.jamesline.com) is the 180-bed adult patient-care component of the cancer program at The Ohio State University. The OSUCCC-James is one of only five centers in the country approved by the NCI to conduct both Phase I and Phase II clinical trials.

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