Vaccine May Prevent Pancreatic Cancer in High-Risk Individuals

mKRAS-VAX, an off-the-shelf synthetic long peptide vaccine, tagets the six most common KRAS mutations found in most pancreatic precancer lesions.

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A Vaccine to Prevent Pancreatic Cancer in High-risk Individuals Was Safe and Elicited Durable Immune Responses

Philadelphia – A vaccine targeting common KRAS mutations was safe and stimulated KRAS-specific T-cell responses in 90% of study participants who were at high risk of developing pancreatic ductal adenocarcinoma (PDAC), according to Phase I clinical trial results published in Cancer Discovery, a journal of the American Association for Cancer Research (AACR).

PDAC is an aggressive cancer that is often diagnosed at advanced stages and carries a low five-year survival rate. Approximately 10% of cases are associated with hereditary predisposition caused by pathogenic mutations in specific cancer susceptibility genes that are passed down from parent to child. The disease evolves over time from precursor lesions such as pancreatic intraepithelial neoplasia and intrapapillary mucinous neoplasms.

“Individuals at high risk due to hereditary predisposition or to the presence of a concerning pancreatic lesion detected on imaging usually undergo surveillance to monitor for changes over time,” said Neeha Zaidi, MD, associate professor of oncology at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, who is one of the corresponding authors of the study. “If there is a high enough concern for transformation to cancer or if early cancer is detected, the current standard of care is surgical resection. However, the chances of recurrence are up to 80%, and many precursor lesions to pancreatic cancer are microscopic and thus undetectable by imaging.”

The team of researchers, including senior authors Elizabeth Jaffee, MD, FAACR, deputy director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, and Michael G. Goggins, MD, professor of pathology, medicine, and oncology and the Sol Goldman Professor of Pancreatic Cancer Research at Johns Hopkins University School of Medicine, reasoned that intercepting cancer development through noninvasive approaches could provide an effective strategy to prevent PDAC and improve survival in high-risk individuals.

“Prevention and interception save lives and reduce the morbidity associated with cancer development and progression. This is especially important for cancers whose early-onset frequency is increasing and for which we do not have effective methods for early detection,” said Jaffee.

“Successful interception that could reduce the occurrence of pancreatic cancer would be a major achievement,” added Goggins.

Mutations in the KRAS gene are the main oncogenic drivers in more than 90% of PDACs. The researchers previously developed mKRAS-VAX, an off-the-shelf synthetic long peptide vaccine targeting the six most common KRAS mutations found in PDAC and in most pancreatic precancer lesions. In the new study, the team conducted a Phase I clinical trial to assess vaccination with mKRAS-VAX in 20 individuals at high risk of PDAC due to hereditary predisposition and radiographic evidence of a pancreatic lesion, typically in the form of a small cyst.

“The goal of this study was to test the safety of the vaccine and induction of durable immune responses,” said Jaffee. She added that the trial was based on preclinical data demonstrating the ability of a KRAS-targeted vaccine to prevent progression of early precancers in a genetically engineered mouse model of KRAS-driven pancreatic cancer.

Study participants received mKRAS-VAX via subcutaneous injections according to a prime-boost vaccination strategy, with priming doses on weeks one, three, and five and a boost dose on week 13. Blood was collected at different time points, and optional annual follow-up visits were offered for long-term immune monitoring.

Results showed that the vaccine stimulated mutant-KRAS-specific effector and central memory T-cell responses in 90% of participants. These responses remained detectable in the blood for up to two years after vaccination. “This long-lasting response is particularly noteworthy when assessing for possible interception of cancer, which requires long-lasting immunity,” said Zaidi. “In addition, the vaccine was safe and well tolerated, supporting its use in larger cancer interception studies.”

After a median follow-up of 16.5 months, none of the vaccinated individuals developed cancer. The researchers evaluated changes in cyst size as an exploratory clinical endpoint and found a higher rate of cyst reduction or resolution among the vaccinated individuals (37.5%) relative to an unvaccinated cohort with similar characteristics (6.8%).

“Overall, this study represents the first proof of concept for the use of vaccines for interception of pancreatic cancer in human patients,” commented Zaidi.

“This research underscores the need for further funding to support the development of strategies that can intercept and prevent cancer development in high-risk individuals. More studies are needed to find the best vaccine approaches, the best targets, and the ideal timing for vaccination,” concluded Jaffee.

According to the authors, the study’s limitations include the small size and the fact that the trial

was not designed to assess the clinical efficacy of the vaccine. “We observed evidence of stability or regression of the pancreatic cysts in association with the induction and durability of KRAS-specific T-cell responses,” said Goggins. “However, larger studies are needed to demonstrate that this effect was in fact due to the vaccine.”

“Furthermore, our immune analysis was limited to peripheral blood. A currently enrolling trial will assess changes in the precancer tissue to determine whether T cells generated by the vaccine are capable of infiltrating the precancer lesions in addition to being detectable in the blood,” added Zaidi.

The study was funded by grants from the National Cancer Institute, the Lustgarten Foundation, and a Stand Up To Cancer (SU2C)-Lustgarten Foundation Pancreatic Cancer Interception Translational Cancer Research Grant (AACR is the Scientific Partner of SU2C).

Goggins declares no conflicts of interest.

Jaffee is chief medical advisor for the Lustgarten Foundation, and cofounder of Abmeta Therapeutics and Adventris Pharmaceuticals. Her scientific advisory board activities include: Mestag Therapeutics, SURGE Therapeutics, Break Through Cancer Foundation, HDT BIO, NEUVOGEN, Candel Therapeutics, Sanofi, and NeoTX. Jaffee reported industry grants from Genentech and Agenus. Jaffee is a founder of, holds equity in, and serves as a consultant to Adventris Pharmaceuticals. Further, Adventris Pharmaceuticals has licensed a technology described in this study from Johns Hopkins University. As a result of that agreement, Jaffee and the university are entitled to royalty distributions related to technology described in the study discussed in this publication. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict-of-interest policies.

Zaidi is a consultant for Genentech. She is also cofounder of, holds equity in, and serves as a consultant to Adventris Pharmaceuticals. Further, Adventris Pharmaceuticals has licensed a technology described in this study from Johns Hopkins University. As a result of that agreement, Zaidi and the university are entitled to royalty distributions related to technology described in the study discussed in this publication. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict-of-interest policies.

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