Trial Watch

Phase II trial of therapeutic pancreatic cancer vaccine

Promising results from a Phase II trial of a therapeutic pancreatic cancer vaccine show improved 1- and 2-year survival compared with historic survival rates.

The trial examined the outcome of 60 patients at the John Hopkins Kimmel Cancer Center (M.D., USA) who received the vaccine in addition to both chemotherapy and surgery. Professionals at the center reported survival rates of 88% at 1 year and 76% at 2 years. Historic 1- and 2-year survival rates are reported to be 60% and 40%, respectively.

The Hopkins vaccine, developed by Elizabeth Jafee of the Kimmel Cancer Center, was engineered to boost the immune response to pancreatic cancer cells that persist after surgery and chemoradiation, and is derived from irradiated cancer cells genetically modified to secrete the immune-stimulatory protein granulocyte–macrophage colony-stimulating factor (GM-CSF). The first vaccine dose is administered 8−10 weeks after surgical resection of the cancer, followed by a 6-month course of radiation and 5-fluoracil-based chemotherapy, with four more doses of the vaccine given at 1-month intervals.

This trial follows an earlier small Phase II trial involving 14 pancreatic cancer patients in which three remain cancer-free more than 7 years after receiving the vaccine. Researchers continue to monitor the 60 patients involved in the more recent trial, and a larger trial including 500−600 patients is planned.

"When compared to the historical data, these patients are doing better with this vaccine, and that is exciting," said Len Lichtenfeld, deputy chief medical officer of the American Cancer Society. "But while we have exciting results, there is a lot of work yet to be done." Lichtenfeld noted that current prospects for pancreatic patients are not good, partly due to the late detection of the disease. The annual incidence of pancreatic cancer in the USA is 32,000, and the number of deaths is approximately the same.

The results of the Sidney Kimmel center study were presented by lead investigator, Daniel Laheru, at the at the 17th International Conference of the American Association of Cancer Research, National Cancer Institute and European Organisation for Research and Treatment of Cancer (AACR-NCI-EORTC) (PA, USA).

Malaria vaccine offers long-term protection

New research has demonstrated that a malaria vaccine developed by GlaxoSmithKline (GSK) can protect children against malaria for a period of at least 18 months.

The Mosquirix® vaccine (RTS,S/AS02A) was tested by a group at the University of Barcelona in more than 1400 Mozambican children, and the results were presented at the Fourth M ultilateral Initiative on Malaria Pan-African Malaria Conference (Yaounde, Cameroon).

In 2003, researchers administered a three-dose regimen of the vaccine to children between 1 and 4 years of age, and then followed them for a period of 18 months to monitor safety and efficacy. The researchers reported a 35% reduction in the incidence of clinical malaria 18 months post vaccination and a 49% reduction in cases of severe or life-threatening malaria. In addition, GSK have reported that vaccinated children were 29% less likely to be infected with the Plasmodium falciparum parasite compared with nonvaccinated children.

In a statement, lead investigator Pedro Alonso said: "The unprecedented response demonstrated in this study is further evidence that an effective vaccine to help control the malaria pandemic...is very possible."

The 18-month results were similar to those reported at 6 months, suggesting that the vaccine does not lose effectiveness over time. Melinda Moree, Director of the nonprofit organization Malaria Vaccine Initiative said, "We are very excited about that, because there is a malaria vaccine that protects children from malaria and it actually lasts long enough to make it a real public health intervention that can have an impact on malaria in Africa."

Mosquirix has already been demonstrated to be safe and efficacious in Phase II trials, and GSK plans to enter into Phase III trials across a number of African cities in 2007, filing for regulatory approval in 2010.

DNA vaccine against HIV

A DNA vaccine against HIV has demonstrated promising results in clinical trials conducted at the Karolinska Institute (Stockholm, Sweden). In a statement released to coincide with World AIDS day (December 1st), researchers reported safety and efficacy data from Phase I trials conducted in 40 HIV-negative individuals.

Britta Wahren, whose group developed the vaccine, commented on the promise from these early results, saying, "There is every reason to be hopeful, even though the study is not finished." Eric Sandstroem, head of clinical testing, said, "It has been more effective than we thought it would be...We have also failed to find any vaccine-related side effects at all."

Phase II of the study, which will test the immune response elicited with the vaccine, is due to end in May or June 2006. The research group hope to carry out Phase III of the trial in Tanzania.

This vaccine is one of more than 30 candidate AIDS vaccines that are being tested worldwide. The International AIDS Vaccine Initiative cites simple and cost-effective production and heat-stability as major advantages of DNA vaccine technology. "There has been scepticism about whether it would in fact be possible to use DNA vaccines for HIV on humans. In that context, our findings are really uplifting," Sandstroem said.

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