

Cancer 'cure' in mice to be tested in humans

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Scientists at Wake Forest University Baptist Medical Center are about to embark on a human trial to test whether a new cancer treatment will be as effective at eradicating cancer in humans as it has proven to be in mice.

The treatment will involve transfusing specific white blood cells, called granulocytes, from select donors, into patients with advanced forms of cancer. A similar treatment using white blood cells from cancer-resistant mice has previously been highly successful, curing 100 percent of lab mice afflicted with advanced malignancies.

Zheng Cui, Ph.D., lead researcher and associate professor of pathology, will be announcing the study June 28 at the Understanding Aging conference in Los Angeles.

The study, given the go-ahead by the U.S. Food and Drug Administration, will involve treating human cancer patients with white blood cells from healthy young people whose immune systems produce cells with high levels of cancer-fighting activity.

The basis of the study is the scientists' discovery, published five years ago, of a cancer-resistant mouse and their subsequent finding that white blood cells from that mouse and its offspring cured advanced cancers in ordinary laboratory mice. They have since identified similar cancer-killing activity in the white blood cells of some healthy humans.

"In mice, we've been able to eradicate even highly aggressive forms of

malignancy with extremely large tumors," Cui said. "Hopefully, we will see the same results in humans. Our laboratory studies indicate that this cancer-fighting ability is even stronger in healthy humans."

The team has tested human cancer-fighting cells from healthy donors against human cervical, prostate and breast cancer cells in the laboratory – with surprisingly good results. The scientists say the anti-tumor response primarily involves granulocytes of the innate immune system, a system known for fighting off infections.

Granulocytes are the most abundant type of white blood cells and can account for as much as 60 percent of total circulating white blood cells in healthy humans. Donors can give granulocytes specifically without losing other components of blood through a process called apheresis that separates granulocytes and returns other blood components back to donors.

In a small study of human volunteers, the scientists found that cancer-killing activity in the granulocytes was highest in people under age 50. They also found that this activity can be lowered by factors such as winter or emotional stress. They said the key to the success for the new therapy is to transfuse sufficient granulocytes from healthy donors while their cancer-killing activities are at their peak level.

For the upcoming study, the researchers are currently recruiting 500 local potential donors who are 50 years old or younger and in good health to have their blood tested. Of those, 100 volunteers with high cancer-killing activity will be asked to donate white blood cells for the study. Cell recipients will include 22 cancer patients who have solid tumors that either didn't respond originally, or no longer respond, to conventional therapies. The study will cost \$100,000 per patient receiving therapy, and for many patients (those living in 22 states, including North Carolina) the costs may be covered by their insurance

company. There is no cost to donate blood. For general information about insurance coverage of clinical trials, go to the American Cancer Society's web site at

www.cancer.org/docroot/ETO/content/ETO_6_2x_State_Laws_Regarding_Clinical_Trials.asp.)

For more information about qualifications for donors and participants, go to www.wfubmc.edu/LIFT (Web site will be available the evening of 6/27.) Cancer-killing ability in these cells is highest during the summer, so researchers are hoping to find volunteers who can afford the therapy quickly.

"If the study is effective, it would be another arrow in the quiver of treatments aimed at cancer," said Mark Willingham, M.D., a co-researcher and professor of pathology. "It is based on 10 years of work since the cancer-resistant mouse was first discovered."

Volunteers who are selected as donors – based on the observed potential cancer-fighting activity of their white cells – will complete the apheresis, a two- to three-hour process similar to platelet donation, to collect their granulocytes. The cancer patients will then receive the granulocytes through a transfusion – a safe process that has been used for more than 30 years. Normally, the treatment is used for patients who have antibiotic-resistant infectious diseases. The treatment will be given for three to four consecutive days on an outpatient basis. Up to three donors may be necessary to collect enough blood product for one study participant.

"The difference between our study and the traditional white cell therapy is that we're selecting the healthy donors based on the cancer-killing ability of their white blood cells," said Cui. The scientists are calling the therapy Leukocyte InFusion Therapy (LIFT).

The goal of the phase II study is to determine whether patients can tolerate a sufficient amount of transfused granulocytes for the treatment. Participants will be monitored on a regular basis, and after three months scientists will evaluate whether the treatment results in clear clinical benefits for the patients. If this phase of the study is successful, scientists will expand the study to determine if the treatment is best suited to certain types of cancer.

Source: Wake Forest University Baptist Medical Center

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