Genetically engineering immune systems to fight melanoma: Clinical trial launched

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Loyola University Medical Center has launched the first clinical trial in the Midwest of an experimental melanoma treatment that genetically engineers a patient's immune system to fight the deadly cancer.

A batch of the immune system's killer T cells will be removed from the patient and genetically modified in a Loyola lab. Two genes will be inserted into the T cells so that they will recognize tumor cells as abnormal.

Patients will undergo high-dose chemotherapy to kill most of their remaining T cells. This will make room for the genetically modified T cells when they are put back in the patient. The modified T cells, it is hoped, will recognize the tumor cells as abnormal and then attack and kill them.

"This clinical trial is a unique attempt to manipulate a person's own immune system to attack their cancer in a more effective and specific manner," said Joseph Clark, MD, one of the principal investigators of the trial.

The purpose of the Phase 1 trial is to determine the optimum dose and whether the treatment is safe. Four doses will be tested, with the highest dose consisting of about 5 billion genetically modified T cells. If Phase 1 demonstrates the treatment is safe, investigators will proceed to Phase 2, which will determine whether the treatment is effective.

Melanoma is the sixth most common cancer in Americans, and the most common fatal malignancy in young adults. Incidence is rising dramatically. About 1 in 50 people will be diagnosed with melanoma. In the 1960s, it was 1 in 600.
Surgery is highly successful if the cancer is caught early. But if the cancer has spread to other parts of the body, the five-year survival rate is only 15 to 20 percent, according to the American Cancer Society.

"This is a terrible, devastating disease," Clark said. "It starts on the skin and can spread to just about anywhere in the body."

The clinical trial is open to patients with metastatic melanoma who are no longer responding to standard therapy. "We need better treatments," Clark said. "Our clinical trial is designed for patients who have no other options."

The experimental immune system therapy was developed by Michael I. Nishimura, PhD, director of the Immunotherapeutics Program at Loyola's Cardinal Bernardin Cancer Center. The cells will be prepared in the Robert R. McCormick Foundation Center for Cellular Therapy in the Cardinal Bernardin Cancer Center.

Nishimura is principal investigator of a five-year, $16.3 million grant from the National Cancer Institute. "Our goal is to create novel therapies for the treatment of advanced malignancies," he said.

Provided by Loyola University Health System