

NON-SCIENTIFIC ABSTRACT OF PROPOSED STUDY

Treatment of patients with metastatic melanoma and renal cell carcinoma has been disappointing. In rare patients, the cancer has spontaneously disappeared. This has suggested that an individual patient's immune system can be capable of fighting the cancer. For these reasons, novel treatments that can increase an individual's immune response against his/her melanoma or renal cell carcinoma are being studied.

The purpose of this study is to evaluate a vaccine made as a result of the new technique called gene therapy. The vaccine is made from tumor cells that have been altered by gene therapy in order to make interleukin-2 (IL-2). Interleukin-2 is a protein made by certain blood cells that can stimulate an immune response. In earlier studies cancer patients have received large doses of IL-2. Some of these patients had reductions in the size or number of their tumors. Most of them experienced side effects, sometimes severe. Many of the side effects were a result of using very high doses. This new technique will use much smaller doses of interleukin-2 to stimulate the immune system to fight the tumor.

The tumor cells used to make the vaccines are stored tumor cells from patients with melanoma or renal cell carcinoma. These cells have a protein called HLA-A2 expressed on the cell surface. Patients will be eligible who express the same protein on their tumor cells. These tumor cells have been induced to produce interleukin-2 by gene therapy. Now, these altered cells can make IL-2 and will be x-rayed to prevent their growth of the tumor cells. These IL-2 secreting tumor cells will be injected in the skin of the thigh of eligible patients.

In this way lymphocytes which have the capability to kill the tumor hopefully are stimulated in vivo. By having access to the systemic blood circulation these lymphocytes can travel to other sides in the body to fight residual tumor.