Have you been diagnosed with Kidney Cancer?

Researchers at the National Institutes of Health (NIH) in Bethesda, Maryland, in partnership with Loyola University Chicago, are enrolling patients with kidney cancer (renal cell carcinoma) into a gene therapy study – a new type of precision medicine that genetically reprograms your immune cells to specifically recognize and kill tumor cells. Immunotherapy has shown to be more effective than the targeted therapies approved for kidney cancer treatment.

T cells are part of the immune system that help protect the body from infection and may help fight cancer. Too often, T cells do not recognize cancer cells or they end up becoming burned-out and lose their fighting ability. The most advanced type of cancer immunotherapy to boost your immune system is gene therapy. It consists of enhancing the T cells from the blood of a patient by genetically reprogramming them in a laboratory. These now "boostered" T cells are given back to the patient allowing the immune system to have clearer directions for recognizing and fighting cancer cells.

Dr. Richard Childs' team discovered that the vast majority of clear-cell kidney cancers have tumor cells that express a protein called HERV-E. When a patient's immune system recognizes this protein, the immune cells are able to kill the cancer cells. With this new gene therapy, we booster your T cells to recognize HERV-E and destroy your tumor cells. This is an early phase trial looking at whether this gene therapy is safe and benefits patients.

During the Study:

- You will undergo leukapheresis, a process to obtain a collection of your immune cells including T cells.
- We will modify these cells in a laboratory through gene therapy to direct them against your cancer.
- You will receive chemotherapy through a vein to prepare your immune system for the modified immune cells.
- Approximately 5 weeks after the leukapheresis, you will be infused with your own immune cells, re-directed to work better at recognizing your tumor.
- You will also receive aldesleukin (IL-2) about every 12 hours for up to 14 doses so your enhanced T cells can grow and have a better chance at killing your tumor.
- You will stay at the Clinical Center, NIH's research hospital for at least 2 weeks after the re-infusion of the boostered T cells.

You may be eligible if:

- You are between the ages of 18 and 70
- You have been diagnosed with kidney cancer type clear cell
- Your disease is metastatic (has spread)

Doctor referral not required.

Study-related tests, procedures, and medications are provided at no cost. Travel within the United States may be reimbursed.

National Heart, Lung, and Blood Institute

NIH...Turning Discovery Into Health®

Location: The NIH Clinical Center, America's Research Hospital is located on the Metro red line (Medical Center stop) in Bethesda, Maryland.

For more information, call:
NIH Clinical Center
Office of Patient Recruitment
1-800-411-1222
TTY: 1-866-411-1010
https://go.usa.gov/xnfkz
NIH study 18-H-0012