

Bergsland

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***A Phase I/II Study of Hepatic Infusion of Autologous CC49-Zeta Gene-Modified T Cells in Patients with Hepatic Metastases from Colorectal Cancer.***

**Non-technical abstract:**

Adenocarcinoma of the large bowel affects approximately 15% of the population of the Western world and is the second most common cause of cancer and cancer-related deaths in the United States. In the United States alone, 155,000 new cases of colorectal cancer are diagnosed per year resulting in 61,500 annual deaths. The most common site of distant metastases is the liver with lung, bone and brain metastases occurring much less frequently. Approximately 75% of patients have liver metastases at the time of death. Despite a modest improvement in the 5-year survival rate of colon cancer patients from 41% to 54% over the past 30 years, a significant unmet medical need for more effective therapy still exists for this disease.

In the proposed clinical study, T cells from the colon cancer patients with liver tumors will be removed, genetically modified outside of the body, and then reinfused back into the individual. The cells will be directly infused into the liver via the hepatic artery. The treatment that the T cells receive will help the T cells recognize and "kill" the cancer cells when the T cells are given back to the patient. The DNA introduced into the T cells encodes a receptor that is made from an antibody that recognizes a tumor-specific marker expressed on colon cancer cells, linked to a signaling chain derived from the human T cell receptor. In this way, Cell Genesys, Inc., has designed a gene that will generate specific immune cells that can recognize a protein on the surface of cancer cells that they might not ordinarily recognize. It is our hope that these gene-modified immune cells will help to eliminate the cancer cells in the patient.