

Non-Technical Abstract

A PHASE I TRIAL OF A CEA-TRICOM BASED VACCINE AND RADIATION TO LIVER METASTASIS WITH OR WITHOUT CELECOXIB IN PATIENTS WITH CEA POSITIVE SOLID TUMORS

Current treatments for cancers that have spread to the liver have not been very effective. Studies in the laboratory using human tumor cells grown in culture dishes and on animals have shown that the use of a specific, genetically altered vaccine with the use of radiation may be effective in killing cancer cells than either vaccine or radiation alone. In addition, we have found an even greater killing of cancer cells when a medication typically used for arthritis pain, celecoxib, is used with the vaccine. Celecoxib may also make radiation kill tumor better.

One way in which the body can fight disease is with its own immune system. For unknown reasons however, the immune system fails to fully recognize proteins made by cancer cells. This may be one reason why cancer may grow or spread. A particular protein called carcinoembryonic antigen (commonly known by the initials CEA) is produced by certain cancer cells and may be a target for the immune system to attack the cancer. We have developed an experimental vaccine in which the genes for CEA have been placed inside a virus vaccine in order for the body to recognize the CEA as a "foreign" invader. This vaccination technique is attempting to increase the body's ability to specifically destroy cancer cells that produce CEA. In this study, patients will be vaccinated against the CEA protein that the tumor produces as well as receive radiation treatment to the site of the liver that the cancer has spread to. Some patients in the study will also receive a pill called celecoxib. All of this is an attempt to help the immune system fight the cancer.

The main focus of this study will be on the safety and tolerance of the vaccines, radiation, and celecoxib in patients who have CEA-producing cancers that have spread to the liver. A total of twelve patients will be enrolled in this study. The twelve patients will be divided into two groups of six patients. The first 6 patients will be placed in Group 1 and will receive vaccine treatment as well as radiation therapy to the liver. The second group of 6 patients will then be placed in Group 2 and will receive the same treatment as Group 1 with the addition of daily celecoxib orally.