
UNIVERSITY OF VIRGINIA HEALTH SYSTEM HUMAN IMMUNE THERAPY CENTER

"Targeting Cancer with the Immune System"

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Clinical Trials

What is a clinical trial?

A clinical trial is used to study new treatments for a variety of cancers as well as other diseases. The Human Therapy Center is focused on developing new treatments that utilize the immune system to fight cancer. The Human Immune Therapy Center has several melanoma clinical trials open at the University of Virginia Health System. The clinical trials are used to answer specific scientific questions and to find new and better ways to help cancer patients.

A majority of clinical trials are based on current therapy. Modifications in clinical trials are used to bring about better treatment for cancer patients. However, even the best results in the laboratory need to be tried in patients to determine if they will have the same outcome.

Clinical Trials are necessary to bring the new

Continued on page 2

INSIDE THIS ISSUE

- 1** What is a clinical trial?
- 1** Cancer Vaccines Developed at Health System Induce Immune Response
- 1** Future Human Immune Therapy Clinical Trial
- 2** Why use a vaccine against cancer?
- 2** Current Clinical Trials
- 2** Calendar of Events

Laboratory Breakthrough at University of Virginia

The search for better treatments for cancer starts in the laboratory as basic research. The best results found in the laboratory are used in clinical trials. The antigens being used in the melanoma clinical trials were discovered in the research laboratories at UVa. In 1994, after three years of basic laboratory investigation, Drs. Slingluff, Engelhard and Hunt identified a peptide that appears on the tumor cells of almost half of all melanoma patients. Since then, three additional peptides have been identified on melanoma by this research team.

The clinical trials have shown cancer cells can be recognized by the immune system through the identification of specific peptide antigens associated with the tumor cells. In one patient, we have seen tumor shrinkage and in many patients we are finding an immune response.

Future Immune Therapy Clinical Trial

The Human Immune Therapy Center is in the final phase of implementing a colon cancer clinical trial early in 2000. We are very excited to be to bring this novel treatment to colon cancer patients. It is based on a European study that showed great promise. The trial will be used to demonstrate that the immune system can be called into action against colon cancer. Colon cancer is the second most frequently diagnosed malignancy in the United States, as well as the second most common cause of cancer death. Standard treatment of colon cancer is surgical resection of the tumor for patients with localized disease. Recurrence following surgery is a major problem and often is the ultimate cause of death. Trials are also being developed for other cancer including breast cancer.

treatment to other patients who are suffering from the same disease. The benefit has to be shown in several patients before it can be used for the treatment of other people with the same type of cancer. Clinical Trials provide the data needed to evaluate the safety and efficacy of new cancer fighting treatments. They also broaden the spectrum of alternatives available to our patients, especially those who have exhausted all of the conventional therapies. The Human Immune Therapy Center will allow a significant expansion of our clinical trial program in immune therapy.

Why use a vaccine against cancer?

A vaccination stimulates the immune system before the pathogen invades and can stimulate a more effective response. The vaccine has helped to control the disease. A vaccine is used to expose your immune system to a similar material that produces an immune resistance to the real thing. The immune resistance against a foreign invader is what we are trying to develop in the Human Immune Therapy Center. The Center is working to help the immune system recognize the cancer cells as invaders that need to be destroyed. When cancer develops, the immune system failed to identify the tumor cells as invaders. Since cancer is a normal cell that has transformed into a tumor cell, the immune system has a hard time recognizing it as an invader. The Center is trying to find the right "map" to give the immune system the ability to find and destroy the cancer cells. The map is the cancer specific antigens located on the surface of the tumor cells. By identification of the antigens unique to the cancer cell, the immune system will know what to look for and destroy.

University of Virginia Health System Melanoma Clinical Trials

Trial for the evaluation of the efficacy of vaccination with synthesized melanoma peptides either pulsed on dendritic cells or administered with GM-CSF in adjuvant plus administration of systemic IL-2 in patients with advanced melanoma. (Mel 31)

Rationale: Vaccines made from melanoma peptide antigens may make the body build an immune response to kill melanoma cells. Colony-stimulating factors such as GM-CSF activate dendritic cells, which present those peptides to the immune system. Interleukin-2 may stimulate a person's white blood cells to kill melanoma cells. Combining vaccine therapy with GM-CSF and interleukin-2 may kill more tumor cells.

Pilot Study for the evaluation of the Efficacy of Vaccination with Autologous Tumor Cells plus GM-CSF-in-Adjuvant, followed by Systemic Low-dose IL-2 Administration, in Patients with High Risk Melanoma (Mel 37)

Rationale: This vaccine is made from melanoma cells taken directly from the patient which are inactivated then used as a vaccine, pulse IL-2 (Interleukin) and GM-CSF.

Trial for the Evaluation of the Effect of Systemic Low-dose IL-2 on the Immunogenicity of a Vaccine Comprising Synthetic Melanoma Peptides Administered with GM-CSF-in-Adjuvant, in Patients with High Risk Melanoma (Mel 36)

Rationale: In an original clinical trial of vaccination with four melanoma peptides, the same peptides that will be used in the current trial, we have observed prominent T-cell responses in the sentinel immunized lymph nodes. However, toxicity associated with the vaccine regimen appears to be largely attributable to the IL-2. Though there is rationale for including IL-2 in the proposed vaccine, its value in this setting is not known. The clinical study proposed here is a pilot study that will test the hypothesis that systemic low-dose IL-2 therapy significantly enhances the immunologic efficacy of a vaccine comprising melanoma peptides plus GM-CSF-in-adjuvant.

If you have any questions regarding these clinical trials please call the University of Virginia Clinical Trials Office at 800-251-3627

CALENDAR OF EVENTS

CRAIG L. SLINGLUFF, JR., M.D.

- ❖ Invited Chair Person at The Keystone Symposium Santa Fe, NM Immunology and Immunology Therapy of Cancer January 2000
- ❖ Invited to Speak on Melanoma at the Meeting of the Society of Surgical Oncology March, 2000

PATRICE NEESE, MSN, ANP

- ❖ Completion of 150 hours of training as a Manual Lymph Drainage Therapist allowing her to assess and treat patients with lymphedema

John Hendrix, M.D.

- ❖ Attending the American Academy of Dermatology meeting in San Francisco March 2000 for special training in whole body skin imaging to detect changes in moles for an earlier detection of potentially dangerous skin lesions.

