	Phase II Randomized Study of CD34+ Derived or Peripheral Monocyte Derived Dendritic Cells Pulsed With MART-1 and gp100 Melanoma Antigens in Patients With High Risk Stage III or Completely Resected Metastatic Melanoma I. Determine the immunologic activity of CD34+ derived and peripheral monocyte derived dendritic cells pulsed with MART-1 and gp100 melanoma antigens in patients with high risk stage III or completely resected metastatic melanoma. PROTOCOL OUTLINE: This is a randomized study. Patients receive dendritic cells derived either from peripheral monocytes or CD34+ cells. Dendritic cells are pulsed with MART-1 and gp100 immunodominant HLA-A201 peptides prior to infusion, and are administered intralymphatically in the lower extremities for the first 2 courses. Beginning with courses 3 and 4, dendritic cells are administered subcutaneously in the anterior thigh. Dendritic cells are not administered to any extremity that has undergone lymph node dissection. Patients are randomized to the following treatment arms: Arm I: Patients undergo leukapheresis to obtain peripheral monocytes. Patients receive dendritic cells derived from peripheral mononuclear cells pulsed with MART-1 and gp100 every 4 weeks for up to 4 courses. Arm II: Patients receive 5 daily subcutaneous injections of filgrastim (G-CSF) followed by leukapheresis on days 5 and/or 6. Patients receive dendritic cells derived from CD34+ cells pulsed with MART-1 and gp100 every 4 weeks for up to 4 courses. Patients are followed at 4 to 6 weeks.	
Active, not recruiting	Vaccine Therapy and Celecoxib in Treating Patients With Metastatic Nasopharyngeal Cancer Condition: Head and Neck Cancer Interventions: Biological: Ad5F35-LMP1/LMP2-transduced autologous dendritic cells; Drug: celecoxib; Other: flow cytometry; Other: immunoenzyme technique; Other: laboratory biomarker analysis	

	Phase II Clinical Trial of Tumour Vaccination By Intradermal Delivery of Autologous Dendritic Cells Transduced With Adenoviral Vector (AD5F35) Expressing Latent Membrane Protein-1 (LMP-1) and Latent Membrane Protein-2 (LMP-2) Genes in Combination With Celecoxib (血管増殖阻害) in Patient With Metastatic Nasopharyngeal Carcinoma. LMP^1 is a viral protein associated with Epstein-Barr virus. Primary: •To evaluate the clinical benefit rate (complete response, partial response, and stable disease for≥ 14 weeks) in patients with metastatic nasopharyngeal carcinoma treated with autologous dendritic cells (DC) transduced with AD5F35 expressing LMP-1 and LMP-2 when administered in combination with celecoxib. Secondary: •To evaluate the toxicities of this regimen in these patients. •To evaluate the specific T-cell response against LMP-1 and LMP-2 as measured by HLA tetramer technology, ELISPOT assay, and delayed-type hypersensitivity in patients treated with this regimen. •To evaluate the surrogate tumor marker response plasma EBV DNA by real-time PCR in these patients. •To evaluate and characterize immunological cell types and tumor characteristics in biopsy specimens of patients treated with this DC vaccine and compare it with pre-vaccine biopsy specimens. •To evaluate progression-free survival and overall survival of patients who show initial clinical benefit to DC vaccine. OUTLINE: Patients undergo blood collection for the preparation of the autologous dendritic cell (DC) vaccine. Immature DCs are transduced with latent membrane protein-1 (LMP-1) and latent membrane protein-2 (LMP-2) using the adenoviral vector 5F35. Beginning 1 week after blood collection, patients receive vaccination with autologous DCs transduced with AD5F35-LMP-1/LMP-2 intradermally every 2 weeks for a total of 5 vaccinations. Patients also receive celecoxib twice a day beginning 1 week before the first vaccination and continuing for up to 6 weeks after completion of the last vaccination. Patients who demonstrate clinical benefit after completion of 5 courses of vaccination may continue to receive the DC vaccine alone off study every 2 weeks until disease progression (based on CT scan findings) or at the investigator's discretion. Patients undergo blood and tumor tissue sample collection periodically for laboratory studies. Blood samples are analyzed using MHC tetramer analysis; enzyme-linked immunospot (ELISPOT) analysis; EBV DNA titers to assess response; and flow cytometry to assess lymphocyte kinetics. Tumor tissue samples are used for immunological studies. Delayed-type hypersensitivity is also assessed. After completion of study treatment, patients are followed monthly for up to 1 year.		
Active, not recruiting	Vaccine Therapy in Treating Patients With Melanoma		
	Condition:	Melanoma (Skin)	
	Interventions:	Biological: HPV 16 E7:12-20 peptide vaccine; Biological: gp100 antigen; Biological: incomplete Freund's adjuvant; Procedure: adjuvant therapy子宮頸部がんの前がん状態の治療、	

	A Pilot Study To Access The Immunologic Response To Booster Vaccination With A Modified gp100 Melanoma Peptide (209-2M) Vaccine In Previously Vaccinated HLA-A2.1+ Patients With Melanoma **OBJECTIVES:** •Determine the toxicity of booster vaccination with gp100:209-217 (210M) peptide and HPV-16 E7 (12-20) peptide vaccine emulsified in Montanide ISA-51 administered at least 12 months after prior vaccination in patients with melanoma. •Determine T-cell response to modified gp100: 209-217 (210M) peptide and unmodified native gp100 peptide in these patients. •Determine T-cell response to the control HLA-A2-restricted CD8 epitope of HPV-16 E7 (12-20) peptide vaccine in these patients. OUTLINE: Patients undergo leukapheresis on day 0. Patients receive vaccination comprising gp100:209-217 (210M) and HPV-16 E7 (12-20) peptide vaccine emulsified in Montanide ISA-51 subcutaneously (SC) on day 1 and between days 25-30 in the absence of disease progression or unacceptable toxicity. Patients undergo a second leukapheresis 2-4 weeks after the second vaccination. Patients who remain disease free for 6 months after the second vaccination may receive additional booster vaccinations SC every 6 months for 3 years. Patients are followed at 3 and 6 months after the second vaccination and then every 6 months thereafter. PROJECTED ACCRUAL: A total of 30 patients will be accrued for this study within 1.5 years.	
Active, not recruiting	Surgery and Vaccine Therapy in Treating Patients With Early Cervical Cancer Condition: Cervical Cancer Interventions: Biological: human papillomavirus 16 E7 peptide; Biological: synthetic human papillomavirus 16 E6 peptide; Procedure: adjuvant therapy; Procedure: surgical procedure; Radiation: radiation therapy	
	Primary Outcome Measures: •Immunological response to HPV, •Toxicity and safety of TA-HPV [Designated as safety issue: Yes] **Secondary Outcome Measures:** •Proliferative capacity of T-cells to the E6 and E7 proteins, •Influence of vaccination with TA-HPV on the disease free interval or patterns of recurrence [Designated as safety issue: No] **OBJECTIVES:** •Evaluate the systemic immunological response to the human papilloma virus vaccine (TA-HPV) expressing the proteins 16, 18, E6 and E7 examining the cytolytic T cell and the antibody responses in cervical cancer patients. •Investigate further the safety and toxic effects of TA-HPV in these patients. •Assess the proliferative capacity of T cells to the E6 and E7 proteins. •Observe any influence of vaccination with TA-HPV on the disease free interval or patterns of recurrence in these patients. OUTLINE: This is an open-label, nonrandomized study. Patients receive 2 vaccinations of the human papilloma virus with proteins 16, 18, E6 and E7 at least 4 weeks apart, with the first vaccination at least 2 weeks before surgery and the second 8 weeks after the first one, unless unacceptable toxicity occurs. Patients who require radiotherapy following surgery receive their second vaccination 4-8 weeks after the first vaccination. Twenty-eight patients are entered initially; if at least 2 patients show an immunologic response, 16 additional patients are entered. Patients are followed every 3 months for 2 years, then every 6 months for 3 years, then annually. PROJECTED ACCRUAL: 44 patients will be entered over 1 year.	
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage II Melanoma That Can Be Removed by Surgery Condition: Melanoma (Skin) Interventions: Biological: gp100 antigen; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Biological: tyrosinase peptide	

	RATIONALE: Vaccines may make the body build an immune response to kill tumor cells. It is not yet known what preparation of vaccine therapy is most effective for treating melanoma. PURPOSE: Randomized phase II trial to study the effectiveness of tyrosinase/gp100 peptide vaccine in treating patients who have stage II melanoma that can be removed by surgery. A Randomized Phase II Trial of a Vaccine Combining Tyrosinase /gp100 Peptides Emulsified With Montanide ISA 51 Alone or With a Block Co-Polymer CRL 1005 or With GM-CSF for Patients With Resected Stages IIA and IIB Melanoma Grant Application Title: MART-1/gp100 Immune Responses to a Melanoma Vaccine OBJECTIVES: I. Determine immune reactivity in HLA-A2 positive patients with resectable stage IIA or IIB melanoma treated with vaccine comprising tyrosinase peptide and gp100 antigen emulsified in Montanide ISA-51 (ISA-51) alone or in combination with GM-CSF. OUTLINE: This is a randomized, multicenter study. Patients are stratified according to stage (IIA vs IIB). Patients are randomized to 1 of 2 treatment arms: Arm I: Patients receive vaccine comprising tyrosinase peptide and gp100 antigen emulsified in Montanide ISA-51 (ISA-51) alone subcutaneously (SQ) once a week on weeks 0, 2, 4, 6, 10, 14, 18, and 26. Arm II: Patients receive treatment as in arm I followed by sargramostim (GM-CSF) SQ for 5 days after each vaccination. Patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter. PROJECTED ACCRUAL: A total of 50 patients (25 per arm) will be accrued for this study within 3 years	
Active, not recruiting	Vaccine Therapy With or Without Cyclophosphamide in Treating Patients Who Have Undergone Surgery for Stage II, Stage III, or Condition: Melanoma (Skin) Interventions: Biological: incomplete Freund's adjuvant; Biological: melanoma helper peptide vaccine; Biological: **multi-epitope melanoma peptide** vaccine; Biological: tetanus toxoid helper peptide; Drug: cyclophosphamide	

	RATIONALE: Vaccines made from peptides may help the body build an effective immune response to kill tumor cells. Drugs used in chemotherapy, such as cyclophosphamide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Cyclophosphamide may also stimulate the immune system in different ways and stop tumor cells from growing. Giving vaccine therapy together with cyclophosphamide after surgery may cause a stronger immune response to kill any remaining tumor cells. It may also prevent or delay the recurrence of melanoma. PURPOSE: This randomized phase I/II trial is studying the side effects of vaccine therapy when given with or without cyclophosphamide and to see how well they work in treating patients who have undergone surgery for stage II, stage III, or stage IV melanoma. **Primary:** •Determine the safety of adjuvant vaccine therapy comprising multi-epitope melanoma peptides (MP) and multi-epitope melanoma helper peptides (MHP) emulsified in Montanide ISA-51 in patients with resected stage IIB-IV melanoma. •Determine the safety of administering cyclophosphamide before vaccination in these patients. •Compare the magnitude of immune response against vaccination comprising MP in combination with either MHP or tetanus toxoid helper peptide (TET) emulsified in Montanide ISA-51 with vs without cyclophosphamide in these patients. **Secondary:** •Compare the response rate and persistence of immune responses in patients treated with these regimens. •Compare the magnitude of immune response against vaccination comprising TET or MHP with vs without cyclophosphamide in patients. •Compare the response rate and persistence of immune response against vaccination comprising TET or MHP with vs without cyclophosphamide in these patients. •Determine the delayed-type hypersensitivity response to the peptide components of these vaccines in these patients. •Compare, preliminarily, disease-free survival of patients treated with these regimens. **OUTLINE**: This is a randomized, open-label, multicenter study. Patients are stratified according to HLA-type(**HLA-A1 positive vs HLA-A2 positive, HLA-A1 negative, or -A3 negative vs HLA-A3 positive, or -A1 negative**) and participating center (University of Virginia [UVA] vs non-UVA). Patients are randomized to 1 of 4 treatment arms. •Arm I: Patients receive vaccine comprising multi-epitope melanoma peptides (MP) and tetanus toxoid helper peptide emulsified in Montanide ISA-51 intradermally (ID) and subcutaneously (SC) on days 1, 8, 15, 29, 36, 43, 85, 183, 274, and 365. •Arm II: Patients receive cyclophosphamide IV over 30-60 minutes on day -4. Patients then receive vaccine as in arm I. •Arm III: Patients receive vaccine comprising MP and multi-epitope melanoma helper peptides emulsified in Montanide ISA-51 ID and SC on days 1, 8, 15, 29, 36, 43, 85, 183, 274, and 365. •Arm IV: Patients receive cyclophosphamide as in arm II. Patients then receive vaccine as in arm III. Treatment in all arms continues in the absence of disease progression or unacceptable toxicity. After completion of study treatment, patients are followed every 6 months for 2 years and then annually thereafter.
Recruiting	Anti-gp100 Cells Plus ALVAC gp100 Vaccine to Treat Advanced Melanoma Conditions: Metastatic Melanoma; Skin Cancer Interventions: Drug: cyclophosphamide ; Drug: fludarabine phosphate

	•gp100 is a protein that is often found in melanoma tumors. •An experimental procedure developed for treating patients with melanoma uses anti-gp100 cells designed to destroy their tumors. The anti-gp100 cells are created in the laboratory using the patient's own tumor cells or blood cells. •The treatment procedure also uses a vaccine called plaque purified **canarypox vector (ALVAC) gp100**, made from a virus that ordinarily infects canaries and is modified to carry a copy of the gp100 gene. The virus cannot reproduce in mammals, so it cannot cause disease in humans. When the vaccine is injected into a patient, it stimulates cells in the immune system that may increase the efficiency of the anti gp 100 cells. **Objectives: -**To evaluate the safety and effectiveness of anti-gp100 cells and the ALVAC gp100 vaccine in treating patients with advanced melanoma. **Eligibility:** -Patients with metastatic melanoma for whom standard treatments have not been effective. **Design:** •Patients undergo scans, x-rays and other tests and leukapheresis to obtain white cells for laboratory treatment. •Patients have 7 days of chemotherapy to prepare the immune system for receiving the gp100 cells. •Patients receive the **ALVAC vaccine, anti-gp100 cells and interleukin-2 (IL-2)** (an approved treatment for advanced melanoma). The anti gp100 cells are given as an infusion through a vein. The vaccine is given as injections just before the infusion of gp100 cells and again 2 weeks later. IL-2 is given as a 15-minute infusion every 8 hours for up to 5 days after the cell infusion for a maximum of 15 doses. •After hospital discharge, patients return to the clinic for periodic follow-up with a physical examination, review of treatment side effects, laboratory tests and scans every 1 to 6 months. Phase II Study of Metastatic Melanoma Using Lymphodepleting Conditioning Followed by Infusion of Anti-gp100:154-162 TCR-Gene Engineered Lymphocytes and ALVAC Virus Immunization
Active, not recruiting	Safety and Immunogenicity of GlaxoSmithKline Biologicals' HPV Vaccine 580299 (Cervarix TM) in HIV Infected Females Conditions: HPV-16/18 Infections; Cervical Neoplasia Interventions: Biological: Cervarix TM; Biological: Placebo Control
Recruiting	Immunization Against Tumor Cells in Sezary Syndrome Conditions: Cutaneous T-Cell Lymphoma; Sezary Syndrome Intervention: Biological: Autologous Dendritic Cell Vaccine
	This research is being done to look at the safety and value of a vaccine for a cancer found in the blood and skin known as Cutaneous T-cell lymphoma (CTCL) and Sezary Syndrome. In the laboratory, researches found that special white blood cells, called dendritic cells (DCs), are able to stimulate the immune system (groups of cells that protect the body from germs and diseases) in a way that helps your body fight cancer. Autologous (from your own body) DCs will be prepared (mixed together) in the laboratory with your cancer cell (Sezary cells) to allow your DCs to pick up parts of your Sezary cells to make the vaccine for you. **Primary Outcome Measures**: •Clinical response (clearance of skin lesions, clinical and radiographic improvement in lymphadenopathy) **Secondary Outcome Measures:** •Biological response, •Survival, •Activities of daily living, •Quality of Life Although the etiology of CTCL is not completely understood, immunologic factors appear to play an important role. Dendritic Cell (DC)-tumor cell vaccines have several features that suggest applications for the immunotherapy of human tumors. Importantly, DC-tumor cell immunization has the potential to simultaneously stimulate CD4+ and CD8+ T cell-mediated immunity against multiple tumor antigens. The vaccine will be prepared from the subject's own blood, obtained during leukapheresis. From leukapheresed blood, monocyte-derived DCs and malignant lymphocytes will be isolated. The DCs will then be loaded with lymphocyte-derived tumor antigens. Formulations and release criteria must be met before vaccine can be administered.
Completed	Gene-Modified White Blood Cells Followed By Interleukin-2 and Vaccine Therapy in Treating Patients With Metastatic

	Condition:	Melanoma (Skin)
	Interventions:	Biological: aldesleukin; Biological: filgrastim; Biological: gp100-fowlpox vaccine; Biological: therapeutic autologous lymphocytes; Biological: therapeutic tumor infiltrating lymphocytes; Drug: cyclophosphamide; Drug: fludarabine phosphate

RATIONALE: Inserting a gene that has been created in the laboratory into a person's white blood cells may make the body build an immune response to kill tumor cells. Interleukin-2 may stimulate a person's white blood cells to kill tumor cells. Vaccines may make the body build an immune response to kill tumor cells. Combining gene-modified white blood cell infusions with interleukin-2 and vaccine therapy may kill more tumor cells.
PURPOSE: This phase I trial is studying how well giving gene-modified white blood cells when given together with interleukin-2 and vaccine therapy works in treating patients with metastatic melanoma.
Primary: •Determine, preliminarily, any clinical tumor regression in lymphodepleted patients with metastatic melanoma treated with**fowlpox gp100 antigen immunization and antitumor antigen T-cell receptor (TCR)-engineered tumor infiltrating lymphocytes or CD8+ autologous peripheral blood lymphocytes followed by interleukin-2.**
Secondary: •Determine the in vivo survival of TCR gene-engineered cells in patients treated with this regimen.
OUTLINE: Patients are stratified according to their ability to produce tumor-infiltrating lymphocytes (TIL) (yes vs no).
Patients receive lymphodepleting chemotherapy comprising cyclophosphamide IV over 1 hour on days -7 and -6 and fludarabine IV over 30 minutes on days -5 to -1.
•Stratum 1 (TIL): Patients receive TIL retrovirally transduced with gp100 antigen TCR gene IV over 20-30 minutes on day 0*.
•Stratum 2 (CD8+peripheral blood lymphocytes [PBL]): Patients receive CD8+PBL retrovirally transduced with gp100 antigen TCR gene IV over 20-30 minutes on day 0*.
NOTE: *Day 0 is 1-4 days after the last dose of fludarabine.
Patients in both strata also receive fowlpox-gp100 vaccine (before TIL/PBL infusion) IV over 1-2 minutes on days 0 and 28 and high-dose interleukin-2 (IL-2) IV over 15 minutes every 8 hours on days 0-4 and days 28-32. Patients also receive G-CSF SC once daily beginning on day 0 and continuing until blood counts recover.
Treatment continues in the absence of disease progression or unacceptable toxicity. Beginning 6-8 weeks after the last dose of vaccine and high-dose IL-2, patients with stable or responding disease may receive 1 retreatment course.
Responding patients are followed at 1, 3, 6, and 12 months and then annually thereafter.
PROJECTED ACCRUAL: A total of 61 patients will be accrued for this study.

Active, not recruiting	Vaccine Therapy in Treating Patients With Metastatic Melanoma	
	Condition: Melanoma (Skin)	
	Intervention: Biological: recombinant vaccinia-TRICOM vaccine	

Active, not recruiting	Injection Of AJCC Stage IIB, IIC, III And IV Melanoma Patients With A Multi-Epitope Peptide Vaccine Using GM-CSF DNA As	
	Condition: Melanoma	
	Intervention: Biological: GM-CSF DNA, NSC 683472 gp100: 209-217(210M), NSC 699048 Tyrosinase: 368-376(370D)	

	Injection Of Melanoma Patients With A Multi-Epitope Peptide Vaccine Using GM-CSF DNA As An Adjuvant: A Pilot Trial To Assess Safety And Immunity **Primary Outcome Measures:** To establish the safety and a recommended dose of subcutaneous human GM-CSF DNA given in conjunction with a multi-epitope peptide vaccine in patients with AJCC stage IIB, IIC, III and IV melanoma who are HLA-A2+. [Time Frame: Up to 15 years post treatment,] [safety issue] To evaluate serum pharmacokinetics of GM-CSF after subcutaneous administration of human GM-CSF DNA. [Time Frame: All patients entered in the Dose Ranging study will undergo pharmacokinetic studies during their first course of therapy.] [Designated as safety issue: Yes] If toxicities are encountered in the dose ranging part of the study, to establish the maximum tolerated dose (MTD) and dose limiting toxicities (DLT). [Time Frame: If toxicities less than DLT are encountered, then patients will continue on the study at the assigned dose level.] In the immunological efficacy study, to evaluate the immunogenicity of a multi-epitope peptide vaccine. [Up to 15 years post treatment.] **Secondary Outcome Measures:** A secondary endpoint is to observe the patients for evidence of any anti-tumor response that is generated after vaccination. [Time Frame: Up to 15 years post treatment] [Designated as safety issue: Yes] **Detailed Description:** This is a pilot trial to investigate the use of GM-CSF DNA as an adjuvant for peptide vaccination in patients with metastatic melanoma.The objective of this study is to determine the safety and adjuvant effect of vaccination with the gene coding for human GM-CSF with a multi-epitope melanoma peptide vaccine (tyrosinase and gp100 peptides) in patients with AJCC stage IIB, IIC, III and IV melanoma who are HLA-A2+. We will assess whether use of GM-CSF DNA is safe and generates an immune response to peptides derived from antigens on melanoma cells. In the Dose Ranging part of the study, cohorts of 3 patients will be treated at increasing dose levels of GM-CSF DNA delivered subcutaneously (100, 400, or 800 ug) followed by administration of both peptides subcutaneously to the same site on day 5 or day 6. Patients will be treated monthly for three immunizations. Pharmacokinetic studies will be performed during the first cycle. Patients' peripheral blood mononuclear cells will be collected in order to measure the T cell responses induced by the vaccines. Toxicity will be assessed during this part of the study, although we do not expect to achieve a dose limiting toxicity (DLT). The dose for the second part of the study will be the maximum tolerated dose. The second part of the study will assess the immunological efficacy of the vaccine. Nine patients will receive GM-CSF DNA delivered subcutaneously at one site, followed by administration of both peptides to the same site on day 5 or day 6, every month for three immunizations. A total of at least 18 patients is planned for both phases of the study. Patients' peripheral blood mononuclear cells will be collected in order to measure the T cell responses induced by the vaccines. Specifically, Elispot assays for CD8+ T cells responses against the peptides will be assessed, and will be the primary method to determine the generation of a specific immune response to the peptide antigens.
Completed	A Study of TroVax Vaccine Given in Conjunction With IL-2 for Treatment of Stage IV Renal Cell Cancer Condition: Carcinoma, Renal Cell Intervention: Biological: TroVax in combination with IL-2

<table>
<tr><td></td><td>The purpose of this study is to test the safety of an investigational vaccine called TroVax when given in conjunction with Interleukin-2 (IL-2) treatment. TroVax is the experimental product in this trial and its value as a medicine has not yet been proven. Interleukin-2 (IL-2) is standard treatment for your cancer, which means that you could receive it even if you choose not to participate in this study. TroVax is being studied as a possible treatment for patients with cancer of the kidney.
TroVax belongs to a class of medicines called a vaccine. A vaccine helps the body's immune system to recognize and kill foreign invading organisms effectively. It is believed that one of the reasons why cancer can spread through the body is that the immune system cannot recognize them as being different from normal tissues and therefore cannot kill the cancer cells. A vaccine that alerts the immune system to the presence of cancer cells in the body could lead to the immune system being able to target and kill those cancer cells effectively. This trial is of a completely new way of trying to treat cancer in the future by the use of vaccination injections. TroVax consists of a virus that has been changed so that it is no longer infectious and carries a gene for a protein called 5T4. This protein is carried by many kidney cancer calls. When the virus is injected, it makes the protein, and the body's immune system is then able to recognize this protein and kill the cells that have it (i.e. the cancer cells).
The purpose of this study is to assess the safety and tolerability of TroVax injections and to understand whether TroVax could make such an immune response happen in patients with renal cell cancer while receiving Interleukin-2 (IL-2). This study will also observe and monitor any side effects experienced in patients who receive TroVax while being treated with IL-2.
Primary Outcome Measures: safety [Time Frame: duration of study] Estimated Enrollment: 25 Study Start Date: August 2004 - : July 2008
Primary Completion Date: July 2008 (Final data collection date for primary outcome measure)
Intervention Details: Biological: TroVax in combination with IL-2 1ml intramuscular injection</td></tr>
<tr><td>Recruiting</td><td><u>Vaccine Therapy in Treating Patients With Metastatic Melanoma</u>
Condition: Melanoma (Skin)
Interventions: Biological: autologous dendritic cell–adenovirus CCL21 vaccine; Other: flow cytometry; Other: fluorescence activated cell sorting; Other: immunoenzyme technique; Other: immunohistochemistry staining method; Other: laboratory biomarker analysis</td></tr>
<tr><td></td><td>A Dose Ranging Trial of Adenovirus CCL-21 Transduced MART-1/gp100 Peptide-Pulsed Dendritic Cells Matured Using Cytokines for Patients With Chemotherapy-Resistant Metastatic Melanoma.
OBJECTIVES: To assess the toxicity and immune responses in patients with HLA-A*0201-positive, chemotherapy-resistant, metastatic melanoma treated with escalating doses of autologous dendritic cell-adenovirus CCL21 vaccine.
To assess clinical responses in these patients.
OUTLINE: Patients receive intradermal injections of autologous dendritic cell-adenovirus CCL21 vaccine once on days 1, 8, 22, and 36. Patients achieving stable disease or response to therapy may receive a second course at least 1 and no more than 6 months from the last vaccine administration.
Blood samples are collected at baseline and after treatment for immunologic studies. Samples are analyzed for MART-1 and gp100-specific CD8+ T-cells and KLH-specific CD4+ T helper cells by ELISPOT assay; cytotoxic T-cells by chromium release assays; and CD8+ T-cells by tetramer-specific flow cytometry and FACS analysis. Patients also undergo tissue biopsies after treatment. Tissue samples are analyzed for numbers of CD3, CD8, CD4 T-cells, CD56 NK, and CD19 B-cells, and levels of local CCL21 by IHC.
After completion of study treatment, patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter.</td></tr>
<tr><td>Completed</td><td><u>Vaccine Therapy in Treating Patients With Advanced Cancer</u>
Condition: Unspecified Adult Solid Tumor, Protocol Specific
Intervention: Biological: TG4010</td></tr>
</table>

	Phase I Bridging Trial of TG4010 as Antigen-Specific Immunotherapy in Patients With MUC-1 Positive Advanced Cancer. Detailed Description: **OBJECTIVES: I.** Determine the safety, tolerance, and maximum tolerated dose of TG4010 in patients with MUC1 positive advanced cancer. II. Determine the biological and immunological effects of this regimen in this patient population. **OUTLINE:** This is a dose escalation study. Patients receive TG4010 IM weekly for 4 weeks, every other week for 8 weeks, and then every 4 weeks. Treatment continues every 4 weeks in the absence of unacceptable toxicity or disease progression. Cohorts of 3-6 patients receive escalating doses of TG4010 until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 3 of 6 patients experience treatment related grade 3 toxicity. If any patient experiences grade 4 toxicity, the prior dose level is considered the MTD. PROJECTED ACCRUAL: A total of 10 patients will be accrued for this study within 4 months
Active, not recruiting	Vaccine Therapy With or Without Sargramostim in Treating Patients Who Have Undergone Surgery for Melanoma Conditions: Intraocular Melanoma; Melanoma (Skin) Interventions: Biological: MART−1 antigen; Biological: gp100 antigen; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Biological: tyrosinase peptide; Procedure: adjuvant therapy
	A Randomized Phase II Continuation Booster Trial After A Vaccine Combining **Tyrosinase/GP100/Mart-1** Peptides Emulsified With Montanide ISA 51 and ISA 51 VG With Or Without GM-CSF For Patients With Resected Stages IIB/C, III And IV Melanoma. **Primary:** Compare immune response in patients with resected stage IIB, IIC, III, or IV melanoma treated with a vaccine comprising tyrosinase peptide, gp100 antigen, and MART-1 antigen emulsified with Montanide ISA-51 and ISA 51 VG with vs without sargramostim (GM-CSF). **Secondary:** Compare time to relapse in patients treated with these regimens. Compare survival of patients treated with these regimens. **OUTLINE:** This is a randomized, parallel, continuation study. Patients are stratified according to response to prior vaccination (response to 1 peptide vs response to 2 or more peptides). Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive vaccination comprising tyrosinase peptide, gp100 antigen, and MART-1 antigen emulsified with Montanide ISA-51 and ISA-51 VG subcutaneously (SC) on day 1 of weeks 0, 26, 52, 78, and 104 (total of 5 vaccinations). Arm II: Patients receive vaccination comprising tyrosinase peptide, gp100 antigen, and MART-1 antigen emulsified with Montanide ISA-51 and ISA-51 VG as in arm I. Patients also receive sargramostim (GM-CSF) SC on days 1-5 of weeks 0, 26, 52, 78, and 104. In both arms, treatment continues in the absence of disease progression or unacceptable toxicity. Patients are followed at 2-4 weeks, every 6 months for 3 years, and then annually thereafter. PROJECTED ACCRUAL: A total of 40 patients (20 per treatment arm) will be accrued for this study within 4 years
Completed	Vaccine Therapy in Treating Patients With Liver Cancer Condition: Liver Cancer Intervention: Biological: AFP (α Fetoprotein)

	A Phase I/II Trial Testing Immunization With Dendritic Cells Pulsed With Four AFP Peptides in Patients With Hepatocellular Carcinoma **Primary Outcome:** Dose limiting toxicity and maximum tolerable dose. [Time Frame: 1 year] **Secondary Outcome:** Generation of AFP specific immunity. [3 years]Progression-free survival. [3 years],clinical response in patients with measurable disease. AFP : Increasing doses of AFP will be given to groups of 3 intradermally. Subjects will receive 3 biweekly vaccinations. At least 2 patients at a given dose must have received their complete 3 vaccination schedule with a 30 day observation period after the last vaccination before a higher dose is initiated. Other Name: AFP peptide-pulsed autologous DC **OBJECTIVES:** Determine the maximum tolerated dose of alpha-fetoprotein peptide-pulsed autologous dendritic cells in HLA-A*0201-positive patientswith hepatocellular carcinoma. Determine the safety and toxicity of this regimen in these patients. Determine the immunological effects of this regimen in these patients. Determine the progression-free survival and clinical responses in patients treated with this regimen. OUTLINE: This is a dose-escalation study. Patients receive alpha-fetoprotein peptide-pulsed autologous dendritic cells intradermally on day 1. Treatment repeats every 2 weeks for a total of 3 doses in the absence of unacceptable toxicity. Cohorts of 3-12 patients receive escalating doses of vaccine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 6 or 2 of 12 patients experience dose-limiting toxicity. Patients are followed at weeks 1, 4, and 12 and then every 6 months thereafter. PROJECTED ACCRUAL: A total of 12-18 patients will be accrued for this study.
Active, not recruiting	Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer Condition: Prostate Cancer Intervention: Biological: therapeutic autologous dendritic cells
	A Safety and Feasibility Study of Active Immunotherapy in Patients With Metastatic Prostate Carcinoma Using Autologous Dendritic Cells Pulsed With Antigen Encoded in Amplified Autologous Tumor RNA **OBJECTIVES: T**he safety and feasibility of autologous dendritic cells transfected with autologous total tumor RNA in patients with metastatic prostate cancer. Determine the presence, frequency, and activation status of tumor specific and prostate specific antigen specific cellular immune responses in patients treated with this regimen. Determine **delayed-type hypersensitivity reactions to PSA protein** and other recall antigens in patients before and after being treated with this regimen. Determine clinical responses based on clinical and biochemical (PSA) response criteria in patients treated with this regimen. Determine a platform for immunological treatment using dendritic-cell based tumor vaccines in these patients. **OUTLINE:** This is a **dose escalation** study. Tumor tissue and peripheral blood stem cells are collected from patients and cultured in vitro with sargramostim (GM-CSF) and interleukin-4 for 7 days to produce dendritic cells (DC). Patients receive autologous DC transfected with autologous prostate carcinoma RNA intradermally once weekly on weeks 0-3 for a total of 4 doses. Cohorts of 3-6 patients receive escalating doses of DC until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 3 or 2 of 6 patients experience dose-limiting toxicity. Patients are followed at weeks 6, 8, 10, and 12; every 3 months for 9 months; and then annually for 2 years. PROJECTED ACCRUAL: A total of 18 patients will be accrued for this study within 20 months.
Completed	Vaccine Therapy in Preventing Cervical Cancer in Patients With Cervical Intraepithelial Neoplasia Conditions: Cervical Cancer; Precancerous Condition

	Intervention: Biological: HspE7	
	Phase II Evaluation Of SGN-00101 (HSP-E7) Fusion Protein In Women With Cervical Intraepithelial Neoplasia 3, CIN 3 **Primary** Determine the efficacy of SGN-00101, in terms of complete histologic regression, in patients with grade III cervical intraepithelial neoplasia. Determine the toxicity of this drug in these patients. **Secondary:** Determine change in lesion size in these patients after treatment with this drug. Compare histologic response before and after treatment with this drug in these patients. OUTLINE: This is a randomized, multicenter study. Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive SGN-00101 subcutaneously once on weeks 1, 4, and 8 in the absence of disease progression. Arm II: Patients receive standard care. At week 15, all patients undergo large loop excision of the transformation zone under colposcopy. Patients are followed at 19 weeks, every 3 months for 1 year, every 6 months for 2 years, and then annually thereafter. PROJECTED ACCRUAL: A total of 28-84 patients (14-42 per treatment arm) will be accrued for this study within 12-48 months.	
Completed	Vaccine Therapy and Interleukin-12 With Either Alum or Sargramostim After Surgery in Treating Patients With Melanoma Conditions: Intraocular Melanoma; Melanoma (Skin) Interventions: Biological: MART-1 antigen; Biological: gp100 antigen; Biological: incomplete Freund's adjuvant; Biological: recombinant interleukin-12; Biological: sargramostim; Biological: tyrosinase peptide; Drug: alum adjuvant; Procedure: adjuvant therapy	
	A Phase II Randomized Trial of a Vaccine Combining Tyrosinase/GP100/MART-1 Peptides Emulsified With Montanide ISA 51 With Interleukin-12 With Alum or GM-CSF for Patients With Resected Stages IIB/C, III and IV Melanoma **OBJECTIVES**: Compare the immune reactivity in patients with resected stage IIB, IIC, III, or IV melanoma vaccinated with tyrosinase, gp100, and MART-1 peptides emulsified with Montanide ISA-51 with interleukin-12 and either alum adjuvant or sargramostim (GM-CSF). OUTLINE: This is a randomized study. Patients are stratified according to disease stage (cutaneous stage IIB, IIC, III, and IV vs ocular and mucosal stage III and IV). Patients are randomized to 1 of 3 treatment arms. Arm I: Patients receive vaccine with tyrosinase:368-376 (370D)/gp100:209-217 (210M)/MART-1:26-27 (27L) peptides emulsified with Montanide ISA-51 (ISA-51), low-dose interleukin-12 (IL-12) subcutaneously (SC), and alum adjuvant SC on day 1 of weeks 1, 3, 5, 7, 11, 15, 19, 27, and 53. Arm II: Patients receive peptide vaccine emulsified with ISA-51, high-dose IL-12 SC, and alum adjuvant SC on day 1 of weeks 1, 3, 5, 7, 11, 15, 19, 27, and 53. Arm III: Patients receive peptide vaccine emulsified with ISA-51 on day 1 and low-dose IL-12 SC and sargramostim (GM-CSF) SC on days 1-5 of weeks 1, 3, 5, 7, 11, 15, 19, 27, and 53. Patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter. PROJECTED ACCRUAL: A total of 60 patients (20 per treatment arm) will be accrued for this study within 3 years.	
Active, not recruiting	Vaccine Therapy in Treating Patients With Resected or Locally Advanced Unresectable Pancreatic Cancer Condition: Pancreatic Cancer Intervention: Biological: MUC-1 antigen/SB AS-2 (adjuvant)	

	Phase I Dose Escalation Trial of a **100 aa Synthetic Mucin Peptide** Admixed With SB-AS2 as Adjuvant in Locally Advanced and Resected Pancreatic Cancer **Detailed Description: OBJECTIVES:** I. Determine the safety and toxicity of vaccination with MUC-1 antigen and immunologic adjuvant SB AS-2 in patients with resected or locally advanced unresectable pancreatic cancer. II. Determine the maximum tolerated dose and/or recommended phase II dose of MUC-1 antigen in this patient population. III. Determine the qualitative and quantitative tumor response to this treatment in these patients. IV. Determine the disease-free survival in resected patients, progression-free survival in locally advanced unresectable patients, and overall survival in all patients receiving this treatment. OUTLINE: This is a dose escalation study of MUC-1 antigen. Patients receive vaccination with MUC-1 antigen and immunologic adjuvant SB AS-2 intramuscularly on day 1. Treatment repeats every 3 weeks for a total of 3 courses in the absence of disease progression or unacceptable toxicity. Beginning 1 year after the last vaccination, patients without recurrent disease may receive booster vaccines annually. Cohorts of 4 to 8 patients receive escalating doses of MUC-1 antigen until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 4 or 2 of 8 patients experience dose-limiting toxicity. Patients are followed at 2 weeks. PROJECTED ACCRUAL: A total of 15-20 patients will be accrued for this study.
Recruiting	Vaccine Therapy in Treating Patients With Malignant Glioma Condition: Brain and Central Nervous System Tumors Intervention: Biological: therapeutic autologous dendritic cells
	Vaccines made from a person's **leukocytes mixed with tumor proteins** may make the body build an immune response to kill tumor cells. PURPOSE: This phase I trial is studying the side effects and best dose of vaccine therapy in treating patients with malignant glioma. Phase I Dose Escalation Study of **Autologous Tumor Lysate-Pulsed Dendritic Cell Immunotherapy** for Malignant Gliomas Primary Outcome : •Dose Limiting Toxicity [Time Frame: 4 weeks] [Designated as safety issue: Yes] Secondary Outcome: •Time to tumor progression, overall survival and cellular immune responses in brain tumor patients injected with tumor lysate pulsed dendritic cells [Time Frame: 2 years] [Designated as safety issue: No] Patients undergo leukapheresis for the collection of peripheral blood mononuclear cells (PBMC). Autologous dendritic cells (DC) are prepared from autologous PBMC exposed to sargramostim (GM-CSF) and interleukin-4 and pulsed with autologous tumor lysate. Patients receive autologous tumor lysate-pulsed DC intradermally on days 0, 14, and 28 in the absence of unacceptable toxicity. Cohorts of 6-12 patients receive escalating doses of autologous tumor lysate-pulsed DC until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 3 or 2 of 6 patients experience dose-limiting toxicity.
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage III or Stage IV Kidney Cancer Condition: Kidney Cancer Interventions: Biological: therapeutic autologous dendritic cells; Procedure: conventional surgery

	Active Immunotherapy of Metastatic Renal Cell Carcinoma Using 自己Dendritic Cells Transfected With Autologous Total Tumor RNA Detailed Description: OBJECTIVES: I. Determine the maximum tolerated dose of autologous dendritic cells transfected with autologous total tumor RNA in patients with stage III or IV renal cell carcinoma. II. Assess the toxicity and feasibility of this treatment regimen in these patients. III. Evaluate this regimen in terms of cellular immune response, clinical response, and overall survival in these patients. OUTLINE: This is a dose-escalation study. Patients undergo nephrectomy for tumor RNA extraction followed by leukapheresis to collect peripheral blood mononuclear cells for dendritic cell (DC) production. Patients receive autologous DC transfected with autologous renal cell carcinoma RNA both IV and intradermally on weeks 0, 2, and 4. Cohorts of 3-6 patients receive escalating doses of DC IV until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 6 patients experience dose-limiting toxicity. Patients are followed every 3 months for 1 year and then every 6 months for 1 year. PROJECTED ACCRUAL: A total of 18 patients will be accrued for this study over 24 months.	
Completed	Vaccination for Patients With High Risk Cancers of the Blood Conditions: Myelodysplastic Syndrome; Acute Myeloid Leukemia (AML); Chronic Myeloid Leukemia (CML) Intervention: Drug: WR 1 and PR 1 Peptide Vaccine	

	This study will determine the safety and effectiveness of an experimental vaccine in controlling the abnormal growth of cells in patients withmyelodysplastic syndrome (MDS, also known as myelodysplasia), **acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL)**, and chronic myeloid leukemia (CML). It will test whether the vaccine can increase the number of immune cells responding to the cancer and thereby slow progression of the illness, improve blood counts, reduce the need for transfusions of blood and platelets, or even achieve a disease remission. The vaccine contains part of a protein that is produced in large amounts by cells of patients with these cancers and an added substance called Montanide that helps the immune system respond to the vaccine. Sargramostim, another substances that boosts the immune response, is also given. Patients 18 to 85 years of age with MDS, AML, ALL or CML may be eligible for this study. Candidates are screened with a medical history, physical examination, blood tests, chest x-ray and bone marrow biopsy. Women of childbearing age also have a pregnancy test. Participants undergo the following: •Chemotherapy entering the study. •Leukapheresis to collect large amounts of white blood cells for infusion before vaccine administration. •Participants may need placement of a central line (plastic tube, or catheter) in the upper part of the chest to be used for giving chemotherapy, blood or platelet transfusions, antibiotics and white blood cells, and for collecting blood samples. •Weekly vaccine injections for nine weeks, given in the upper arm, upper leg or abdomen. •Sargramostim injections following each vaccination. •Standard of care treatment for MDS, AML, ALL or CML, which may include blood or platelet transfusions, growth factors, and drugs to control underlying disease and potential side effects of the vaccine. •Weekly safety monitoring, including vital signs check, brief health assessment, blood tests and observation after the vaccination, on the day of each vaccination. •Follow-up evaluations with blood tests and chest x-ray 3 weeks after the last vaccine dose and with blood tests and bone marrow biopsy 7 weeks after the last vaccine dose. **Primary Outcome Measures:** •The primary objectives will to evaluate the efficacy and toxicity associated with the immunotherapy approach of lymphodepletion, lymphocyte infusion, and **WT1 vaccination** in selected patients with hematological malignancies. [Time Frame: 12 weeks] **Secondary Outcome**: •Secondary objectives will include evaluation of disease response by following the numbers of WT1 expressing cells in blood, hematological measurements (reduction in marrow blast cells, changes in blood counts), transfusion dependence, and time t... [Time Frame: 12 weeks of planned peptide vaccine research, which will evaluate the safety associated with an immunotherapy approach of lymphodepletion, lymphocyte infusion, and WT1 vaccination in select patients diagnosed with MDS, AML, ALL and CML. The WT1 vaccination will comprise of 9 doses of WT-1 peptide vaccines (in Montanide adjuvant) administered concomitantly with GM-CSF (Sargramostim). The primary objectives will be to evaluate the efficacy and toxicity associated with the immunotherapy approach of lymphodepletion, lymphocyte infusion, and WT1 vaccination in selected patients with hematological malignancies. Secondary objectives will include evaluation of disease response by following the numbers of WT1 expressing cells in blood, hematological measurements (reduction in marrow blast cells, changes in blood counts), transfusion An **HLA-A0201 restricted WT-1 peptide**
Active, not recruiting	Peptide Vaccine Targeting to Cancer Specific Antigen Combined With Anti-angiogenic Peptide Antigen in Treating Patients Condition: Non Small Cell Lung Cancer Intervention: Biological: HLA-A*2402restricted URLC10, CDCA1, VEGFR1 and VEGFR2

	Phase I Trial in Studying Peptide Vaccine Therapy Targeting to Cancer Specific Antigen Combined With Anti-**angiogenic Peptide Antigen** in Treating Patients With Advanced or Recurrent Non-small Cell Lung Cancer **Primary:** Adverse effects, dose limiting toxicity, and maximum tolerated dose as measured by CTCAE ver3.0 pre treatment, during study treatment, and 3 months after treatment. **Secondary**: Peptides specific **CTL responses** in vitro [3 months], Objective response rate as assessed using RECIST criteria [6 months] , Changes in levels of regulatory T cells [3 months] Biological: **HLA-A*2402**restricted URLC10, CDCA1, VEGFR1 and VEGFR2 Escalating doses of every peptide will be administered by subcutaneous injection on days 1,8,15 and 22 of each 28-day treatment cycles. Planned doses of peptides are 1.0mg and 3.0mg. Detailed Description: URLC10 and CDCA1 have been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. We have determined the HLA-A*2402 restricted epitope peptides derived from these molecules. We also tend to use the peptides targeting to tumor angiogenesis. VEGF receptor 1 and 2 are essential targets to tumor angiogenesis, and we identified that peptides derived from these receptors significantly induce the effective tumor specific CTL response in vitro and vivo. According to these findings, in this trial, we evaluate the safety, immunological and clinical response of those peptides.	
Completed	Vaccine Therapy in Treating Young Patients Who Are Undergoing Surgery for Malignant Glioma Condition: Brain and Central Nervous System Tumors Interventions: Biological: therapeutic autologous dendritic cells; Procedure: adjuvant therapy; Procedure: therapeutic conventional surgery	
	Phase I Dose Escalation Study of **Autologous Tumor Lysate-Pulsed Dendritic Cell** Immunotherapy for **Malignant Gliomas** in Pediatric Patients **Primary:** Determine the dose-limiting toxicity of adjuvant vaccination with autologous tumor lysate-pulsed dendritic cells after surgical resection in pediatric patients with malignant glioma. Determine the maximum tolerated dose of this vaccine in these patients. **Secondary:** 1.Determine, preliminarily, the survival of patients treated with this vaccine. 2) Determine, preliminarily, the time to tumor progression in patients treated with this vaccine. 3) Determine cellular immune response in patients treated with this vaccine. 4) Determine age-dependent differences in response to this vaccine, in terms of immunocompetence, in these patients. OUTLINE: This is a dose-escalation study. Patients undergo surgical resection to obtain tumor tissue for production of tumor lysate. Patients then undergo leukapheresis to obtain peripheral blood mononuclear cells (PBMC) for generation of dendritic cells (DC). DC are pulsed with tumor lysate to produce an autologous dendritic cell vaccine. Approximately 10-30 days after leukapheresis, patients receive vaccination with autologous tumor lysate-pulsed dendritic cells intradermally on days 0, 14, and 28 in the absence of disease progression or unacceptable toxicity. Cohorts of 3-6 patients receive escalating doses of vaccine until the maximum tolerated dose (**MTD**) is determined. The MTD is defined as the dose preceding that	
Completed	Vaccine Therapy Plus QS21 in Treating Patients With Small Cell Lung Cancer That Has Responded to Initial Therapy Condition: Lung Cancer Interventions: Biological: QS21; Biological: keyhole limpet hemocyanin (KLH); Drug: polysialic acid	

	Immunization Using Polysialic Acid-KLH or N-Propionylated Polysialic Acid-KLH Conjugate Plus the Immunological Adjuvant QS-21 in Patients With Small Cell Lung Cancer Who Have Achieved a Major Response to Initial Therapy OBJECTIVES: I. Compare the antibody response after immunization with polysialic acid keyhole limpet hemocyanin (PSA-KLH) conjugate or N-propionylated PSA-KLH conjugate plus immunological adjuvant QS21 in patients with small cell lung cancer. II. Assess the clinical toxicities resulting from these regimens and from the immune response in this patient population. OUTLINE: Patients receive polysialic acid keyhole limpet hemocyanin (PSA-KLH) conjugate or N-propionylated PSA-KLH conjugate plus immunological adjuvant QS21 subcutaneously weekly on weeks 1-4 and on weeks 8 and 16 for a total of 6 vaccinations. Patients are followed at 2 weeks, and then every 3 months for up to 1 year. PROJECTED ACCRUAL: A total of 12 patients will be accrued for this study	
Recruiting	Vaccine Therapy in Treating Patients With Recurrent B-Cell Lymphoma Condition: Lymphoma Interventions: Biological: plasmid DNA vaccine therapy; Other: flow cytometry; Other: immunoenzyme technique	
	Phase I Trial to Assess Safety and Immunogenicity of Xenogeneic CD20 DNA Vaccination With Patients With B-Cell Lymphoma **Primary:** To evaluate the safety and feasibility of intramuscular DNA vaccination with a plasmid DNA vector expressing the mouse extracellular domain of CD20 (pING-mminiCD20). To determine the optimal biological dose of this vaccine. **Secondary:** To evaluate antibody and T-cell responses to CD20 after vaccination. To observe patients for evidence of any antitumor response generated after vaccination. OUTLINE: Patients receive xenogeneic CD20 DNA vaccine intramuscularly on day 1. Treatment repeats every 21 days for 5 courses in the absence of disease progression or unacceptable toxicity. Blood is collected after the second dose of vaccine and after completion of study treatment. Samples are analyzed for antibody and T-cell responses by flow cytometry, ELISPOT assay, and major histocompatibility complex tetramer assays. After completion of study treatment, patients are followed for up to 2 years.	
Completed	Vaccine Therapy in Treating Patients With Cancer of the Gastrointestinal Tract Conditions: Colorectal Cancer; Esophageal Cancer; Extrahepatic Bile Duct Cancer; Gallbladder Cancer; Gastric Interventions: Biological: carcinoembryonic antigen peptide 1-6D; Biological: incomplete Freund's adjuvant; Biological:	

	A Trial Of Vaccination With The Carcinoembryonic Antigen **(CEA) Peptide Cap 1-6D** With **Montanide ISA 51** Adjuvant Or Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) In HLA-A2+ Patients With CEA Producing Adenocarcinomas Of Gastrointestinal (GI) Tract Origin **Primary: 1) Production of CAP 1-6D T cells.**2) **Production of cytotoxic T cells.** 3) **Antitumor response.** 4) Frequency and severity of toxic effects **OBJECTIVES: 1)** Determine whether immunization with carcinoembryonic antigen (CEA) peptide 1-6D (CAP 1-6D) emulsified in Montanide ISA-51 adjuvant or dissolved in sargramostim (GM-CSF) can generate CAP 1-6D-specific T cells in patients with CEA-producing adenocarcinomas of gastrointestinal tract origin. 2) Determine whether vaccination with CAP 1-6D can generate cytotoxic T cells against CEA-expressing tumors in these patients. 3) Determine whether this vaccine can produce antitumor responses in these patients. 4) Determine the frequency and severity of toxic effects associated with this vaccine in these patients. **OUTLINE:** This is a randomized study. Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive carcinoembryonic antigen peptide 1-6D (CAP 1-6D) emulsified in Montanide ISA-51 adjuvant subcutaneously on day 1. Arm II: Patients receive CAP 1-6D dissolved in sargramostim **(GM-CSF)** intradermally on day 1. Treatment repeats in both arms every 3 weeks for 6 courses in the absence of disease progression or unacceptable toxicity. Patients are followed at 3 weeks and then as necessary. PROJECTED ACCRUAL: A total of 10-36 patients (5-18 per arm) will be accrued for this study within 36 months	
Completed Has Results	Human Papilloma Virus (HPV) Vaccine Trial in Young Adolescent Women With GlaxoSmithKline Biologicals' (GSK Bio) HPV-		
	Conditions:	Papillomavirus Infection; Cervical Intraepithelial Neoplasia	
	Interventions:	Biological: GSK Biologicals' HPV-16/18 Vaccine (Cervarix™); Biological: Havrix™	
Recruiting	Evaluation of Safety of a Vaccine Against Cervical Cancer in Healthy Korean Females		
	Conditions:	HPV-16/18 Infections and Associated Cervical Neoplasia; Papillomavirus Vaccines	
	Intervention:	Biological: Cervarix.	
Recruiting	Follow-Up Evaluation of Patients With Solid Tumors Previously Enrolled in a Vaccine Therapy Clinical Trial		
	Conditions:	Breast Cancer; Colorectal Cancer; Long-term Effects Secondary to Cancer Therapy in Adults; Metastatic 2007-2012 Cancer; Ovarian Cancer; Prostate Cancer; Unspecified Adult Solid Tumor, Protocol Specific	
	Interventions:	Other: follow-up care; Procedure: assessment of therapy complications; Procedure: examination	

	This study aims to provide long-term follow-up care of patients previously enrolled in a vaccine study that involved poxviral vectors. Vectors are sequences of genetic material that can be used to introduce specific genes into genetic makeup. The study does not involve the use of any drug or biologic agent. Participants will undergo an annual health history. Because certain viruses enter into cells and create proteins from the viral genes, the type of vaccine treatment used is referred to gene therapy. The genes expressed by poxviral vectors do not become part of the genetic material left behind. Because gene therapy is a somewhat new technology, a prolonged monitoring of patients' health status is necessary, according to new specific reporting requirements for harmful events in patients who undergo such gene therapy studies. The risk of any long-term negative effects from the gene therapy that patients had received is quite small. Still, it is important that there be updates at least annually. This annual monitoring of health status will extend for 15 years, according to guidelines from the Food and Drug Administration, or for as long as patients are willing to participate. Patients who received poxviral vectors (vaccinia or fowlpox, or both) at the National Cancer Institute, through a trial affiliated with the Laboratory of Tumor Immunology and Biology, may be eligible for this study. Participants will be involved in the following forms of data collection: Annual medical history and physical examinations for the first 5 years following the last vaccine. Annual telephone contact during the last 10 years. Health status check, including primary cancer status, secondary malignancies, neurologic disorders, autoimmune disorders, and hematologic disorders. Blood tests for the presence of HIV antibodies. Reporting of medical problems, including information on unexpected hospitalizations and medications. If a participant has died, the study will document the cause of death and autopsy information if available.
Completed	Vaccine Therapy in Treating Patients With Refractory Stage IV Cancer Condition: Unspecified Adult Solid Tumor, Protocol Specific 2003–2011 Interventions: Biological: CMV pp65 peptide; Biological: carcinoembryonic antigen peptide 1–6D; Biological: therapeutic autologous dendritic cells
	A Phase I Study of Active Immunotherapy With CAP-1 (6D) and CMVpp65 Peptide-Pulsed, Autologous Dendritic Cells Produced in the Aastromreplicell Cell Production System in Patients With Stage IV CEA Expressing Malignancies. **OBJECTIVES:** Determine the safety and feasibility of administering 1 or 2 courses of vaccination with carcinoembryonic antigen peptide 1-6D (CAP 1-6D)- and CMV pp65 peptide-pulsed autologous dendritic cells in patients with refractory stage IV CEA-expressing malignancies. Determine the ability of this regimen to induce CAP 1-6D- and CMV pp65-specific T cells in these patients. Determine the antitumor effect of this regimen, in terms of progression-free survival, of these patients. **OUTLINE:** This is an open-label, dose-escalation study. Patients undergo leukapheresis and collection of peripheral blood monocytes from whichdendritic cells (DC) are generated and pulsed with carcinoembryonic antigen peptide 1-6D (CAP 1-6D) and CMV pp65 peptide. Patients are assigned to 1 of 2 vaccination cohorts. Cohort I: Patients receive vaccination with CAP 1-6D-pulsed DC and CMV pp65 peptide-pulsed DC subcutaneously and intradermally every 3 weeks for a total of 4 vaccinations. Cohort II: Patients receive vaccinations as in cohort I every 3 weeks for a total of 8 vaccinations. For both cohorts, a safe dose of the vaccine is defined as the dose at which no more than 1 of 6 patients experiences unacceptable toxicity. Patients are followed every 3 months for 1 year.
Terminated	Vaccine Therapy and GM-CSF in Treating Patients With Progressive Non-Hodgkin's Lymphoma Condition: Lymphoma 2005–2010

	Interventions: Biological: autologous immunoglobulin idiotype-KLH conjugate vaccine ; Biological: sargramostim	
	Phase II Trial of FavId™ (Patient-Specific Idiotype/KLH) and GM-CSF in Subjects Who Demonstrated Progressive Disease and Did Not Receive FavId on Study FavId-06 **Primary:** Provide treatment with autologous immunoglobulin idiotype-KLH conjugate vaccine (FavId)™ and sargramostim (GM-CSF) to patients with progressive grade 1, 2, or 3 follicular B-cell non-Hodgkin's lymphoma who did not receive FavId™ while enrolled on protocol FAV-ID-06. **Secondary:** Determine the response rate and duration of response in patients treated with this regimen. Determine the response rate and response rate improvement after best response to prior salvage therapy in patients treated with this regimen. Determine the time to progression in patients treated with this regimen. Determine the safety of this regimen in these patients. OUTLINE: This is a multicenter study. Patients are assigned to 1 of 2 groups according to timing of disease progression while enrolled on protocol FAV-ID-06 (disease progression after prior rituximab AND never randomized vs disease progression after randomization to placebo arm). Patients receive autologous immunoglobulin idiotype-KLH vaccine subcutaneously (SC) on day 1. Patients also receive sargramostim (GM-CSF) SC on days 1-4. Treatment repeats monthly for 6 months in the absence of disease progression or unacceptable toxicity. Patients with stable or responding disease may receive additional treatment as above every 2 months for 1 year (6 treatments) and every 3 months until disease progression. After completion of study treatment, patients are followed for 30 days or until the start of subsequent treatment. PROJECTED ACCRUAL: Approximately 238 patients (67 in group I and 171 in group II) will be accrued for this study.	
Recruiting	Trial of a WT-1 Analog Peptide Vaccine in Patients With Acute Myeloid Leukemia (AML) Condition: Acute Myeloid Leukemia 2010-2012 Intervention: Biological: WT1 peptide vaccine	
	Phase II Trial of a **WT-1 Analog Peptide** Vaccine in Patients in Complete Remission (CR) From Acute Myeloid Leukemia (AML) or Acute Lymphoblastic Leukemia (ALL) **Primary**: 1) To assess the safety [at weeks 2 and 4 with routine toxicity throughout the trial], of the WT1 peptide vaccine administered to patients in CR from AML. Early toxicity will be assessed at weeks 2 and 4,. Routine toxicity assessments will continue throughout the trial. Any toxicity noted in the trial will be graded in accordance with Common Toxicity Criteria, version 4.0 (CTCAE 4.0) developed by the National Cancer Institute. 2) To assess the efficacy of the WT1 peptide vaccine administered to patients in CR from AML. [3 years] The primary efficacy measure is defined as overall survival at 3 years. **Secondary: 1) Disease free survival [3 years**], 2) To assess the immunologic responses of vaccine administration [at week 12], via **CD4+ T cell proliferation, CD3+ T cell interferon- γ release (ELISPOT and / or flow cytometry)** and **WT1 peptide tetramer staining**. 3) •To assess any effect **on minimal residual disease [at week 12] as measured by RT-PCR for WT1 transcript** **Biological: WT1 peptide vaccine** Six vaccinations of the **WT1 peptide preparation** (1.0 ml of emulsion) will be **administered on weeks 0, 2, 4, 6, 8, and 10**. All vaccinations will be administered subcutaneously with vaccination sites rotated among extremities. Patients who are clinically stable and have not had disease progression may **receive up to 6 more vaccinations administered appropriately every month**	
Completed	Vaccine Therapy in Treating Patients With Stage I, Stage II, or Stage IIIA Non-small Cell Lung Cancer or With Stage I or Stage Conditions: Lung Cancer; Malignant Mesothelioma 1999-2011 Interventions: Biological: lung tumor associated antigen; Drug: DetoxPC; Drug: chemotherapy; Drug: cyclophosphamide	