

Completed	Vaccine Therapy Plus Chemotherapy in Treating Patients With Metastatic or Locally Recurrent Stomach Cancer or Esophageal		
	Conditions:	Esophageal Cancer; Gastric Cancer	
	Interventions:	Biological: G17DT Immunogen; Drug: cisplatin; Drug: fluorouracil	
	<p>RATIONALE: Vaccines may make the body build an immune response to kill tumor cells. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining vaccine therapy with chemotherapy may kill more tumor cells.</p> <p>PURPOSE: Phase II trial to study the effectiveness of combining vaccine therapy and chemotherapy in treating patients who have metastatic or locally recurrent stomach cancer or esophageal cancer.</p> <p>Primary Outcome Measures: •To determine whether a concomitant G17DT-chemotherapy regimen affects tumor response in subjects with gastric or gastroesophageal cancer. [Time Frame: 6 months to 1 year] [Designated as safety issue: No]</p> <p>Secondary Outcome Measures: •Time to disease progression, best overall response, and survival will be evaluated in the intent-to-treat population and the evaluable population. [Time Frame: 6 months to 1 year]</p> <p>OBJECTIVES: I. Determine a safe and immunogenic combination of G17DT with cisplatin and fluorouracil in patients with chemotherapy-naïve metastatic or locally recurrent gastric or gastroesophageal cancer. II. Determine the safety profile and tolerability of this regimen in these patients. III. Determine the tumor response rate, disease stabilization, best overall response, time to progression, time to treatment failure, and overall survival in patients treated with this regimen. IV. Determine the correlation of immunological response with clinical efficacy and benefit in patients treated with this regimen. V. Determine the pharmacokinetics and pharmacodynamics of this regimen in these patients.</p> <p>OUTLINE: This is a multicenter study. Patients are assigned to one of four treatment regimens. Regimen A: Patients receive high-dose G17DT intramuscularly (IM) on days 7, 35, and 63. Patients also receive cisplatin IV over 1-3 hours on day 1 followed by fluorouracil IV continuously over days 1-5 every 4 weeks in the absence of disease progression or unacceptable toxicity. If inadequate immune response is seen on Regimen A, subsequent patients are treated on Regimen B. If unacceptable toxicity is seen on Regimen A, subsequent patients are treated on Regimen C. If inadequate immune response and unacceptable toxicity are seen on Regimen A, or if unacceptable toxicity is seen on Regimen B or inadequate immune response is seen on Regimen C, then subsequent patients are treated on Regimen D. Regimen B: Patients receive high-dose G17DT IM on days 1, 28, and 56. Patients also receive cisplatin IV over 1-3 hours on day 35 followed by fluorouracil IV continuously over days 35-39 every four weeks in the absence of disease progression or unacceptable toxicity. Regimen C: Patients receive low-dose G17DT IM on days 7, 35, and 63 with chemotherapy as in regimen A. Regimen D: Patients receive low-dose G17DT IM on days 1, 28, and 56 with chemotherapy as in regimen B. Quality of life is assessed at baseline, on day 7, every 2 weeks for 10 weeks, and then every 4 weeks thereafter.</p> <p>PROJECTED ACCRUAL: A total of 15-75 patients will be accrued for this study within 5-30 months.</p>		
Recruiting	Melanoma Vaccine in Treating Patients With Stage III Melanoma After Surgery to Remove Lymph Nodes		
	Condition:	Melanoma (Skin)	
	Interventions:	Biological: HLA-A1-binding MAGE-1/MAGE-3 multipeptide-pulsed autologous dendritic cell vaccine; Biological: HLA-A2-binding TYR/MART-1/gp100 multipeptide-pulsed autologous dendritic cell vaccine; Biological: autologous melanoma lysate-pulsed autologous dendritic cell vaccine; Biological: autologous melanoma lysate/KLH-pulsed autologous dendritic cell vaccine; Biological: dendritic cell-idiotypic-keyhole limpet hemocyanin vaccine; Other: flow cytometry; Procedure: adjuvant therapy	

	<p>Primary Outcome Measures: •Immune response, •Disease-free survival , •Overall survival, •Adverse events</p> <p>OBJECTIVES: •Determine the feasibility of adjuvant melanoma vaccine comprising autologous dendritic cells pulsed with tumor antigen peptides in patients with stage III melanoma following lymphadenectomy.</p> <p>•Determine the immune response (skin test of delayed-type hypersensitivity and flow cytometric enumeration of peripheral blood CD8+ lymphocytes producing IFN-γ) to this regimen in these patients.</p> <p>•Determine clinical outcome (disease-free survival, overall survival, and adverse events) in patients treated with this regimen.</p> <p>OUTLINE: Patients undergo leukapheresis for collection of peripheral blood mononuclear cells (PBMCs) and bone marrow mononuclear cells. Autologous dendritic cells (DCs) prepared from PBMCs and bone marrow mononuclear cells are exposed to various antigens and peptides, and autologous tumor cell lysate, if available. Patients receive autologous DCs pulsed with melanoma-associated antigen peptides, and autologous DCs pulsed with tumor lysates (if available), subcutaneously in weeks 0, 2, 5, 8, 12, 16, 20, 26, 31, 50, and 102. Patients with no evidence of disease may receive another booster injection 5 years after the start of vaccination. Blood samples are examined via flow cytometry and skin testing is performed to evaluate immune response.</p>	
Recruiting	<p>Trial of Activated Marrow Infiltrating Lymphocytes Alone or in Conjunction With an Allogeneic Granulocyte Macrophage</p>	
	Condition:	Multiple Myeloma
	Interventions:	Biological: aMILs; Biological: Allogeneic Myeloma Vaccine
	<p>Primary Outcome Measures: •Response rate utilizing Blade' criteria [Designated as safety issue: No]</p> <p>Secondary Outcome Measures: •Progression-free and overall survival [Designated as safety issue: Yes]</p> <p>•Anti-tumor immune response [Designated as safety issue: No]</p> <p>•The effect of aMILs on osteoclastogenesis [Designated as safety issue: No]</p> <p>•Effect of Marrow Infiltrating Lymphocytes on clonogenic myeloma precursors [Designated as safety issue: No]</p> <p>Estimated Enrollment: 32 Study Start Date: December 2009</p> <p>Estimated Primary Completion Date: December 2012 (Final data collection date for primary outcome measure)</p> <p>Exp.1 Biological: aMILs: Activated marrow infiltrating lymphocytes</p> <p>Exp.2 Biological: aMILs Activated marrow infiltrating lymphocytes VER. Biological: Allogeneic Myeloma Vaccine</p> <p>Allogeneic granulocyte macrophage colony-stimulating factor (GM-CSF)-based myeloma cellular vaccine</p>	
Completed	<p>Trial of Autologous, Hapten-Modified Vaccine in Patients With Stage III or IV Melanoma</p>	
	Condition:	Melanoma
	Interventions:	Biological: Autologous, DNP-modified vaccine (M-Vax); Biological: Autologous, DNP-Modified Melanoma Vaccine; Biological: Autologous, DNP-Modified Vaccine
	<p>The purpose of this study is to determine whether a vaccine composed of patients' own melanoma cells treated with the chemical, dinitrophenyl (DNP)(called a hapten), is safe and stimulates an immune response to patients' own cancer cells.</p> <p>Primary Outcome Measures: •Immune response to patients' own melanoma cells [Time Frame: 2 months] [Designated as safety issue: No]</p> <p>Secondary Outcome Measures: •Safety [Time Frame: 9 months] [Designated as safety issue: Yes]</p> <p>M-Vax: A Feasibility and Bio-Equivalence Study Using a DNP-Modified Autologous Melanoma Tumor Cell Vaccine as Therapy in Patients With Stage III or IV Melanoma</p>	
Completed	<p>Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy</p>	
Has Results	Condition:	Prostate Cancer
	Interventions:	Biological: sipuleucel-T; Biological: Placebo

	<p>Primary Outcome Measures: •Time to Objective Disease Progression [Time Frame: 36 months from randomization] [Designated as safety issue: Yes] The time to objective disease progression in patients with asymptomatic metastatic hormone-refractory prostate cancer treated with APC8015 (sipuleucel-T). Secondary Outcome Measures: •Overall Survival [Time Frame: From randomization to 36 months] [Designated as safety issue: Yes] Overall Survival Biological: sipuleucel-T : Autologous peripheral blood mononuclear cells, including antigen presenting cells, that have been activated in vitro with a recombinant fusion protein, PAP-GM-CSF. Treatment consist of 3 doses administered approximately 2 weeks apart. Other Name: APC8015, Provenge Biological: Placebo: Approximately one-third of the autologous quiescent antigen presenting cells (APCs) prepared from a single leukapheresis procedure. A course of therapy consists of 3 complete doses given at approximately 2-week intervals.</p>	
Active, not recruiting	Interferon-gamma or Aldesleukin and Vaccine Therapy in Treating Patients With Multiple Myeloma	
	Condition:	Multiple Myeloma and Plasma Cell Neoplasm
	Interventions:	Biological: aldesleukin; Biological: idiotype-pulsed autologous dendritic cell vaccine APC8020; Biological: recombinant interferon gamma; Genetic: polymerase chain reaction; Genetic: reverse transcriptase-polymerase chain reaction; Other: flow cytometry; Other: laboratory biomarker analysis
	<p>Primary •To assess the clinical benefit in patients with plateau phase multiple myeloma treated with interferon-gamma vs aldesleukin in combination with idiotype-pulsed autologous dendritic cell vaccine APC8020. •To describe response rates in patients who are in plateau phase status post-chemotherapy or status post-peripheral blood cell transplantation treated with this regimen. Secondary: •To obtain data regarding the ability of this approach to produce an anti-idiotypic immunologic response. •To obtain information about the effects of interferon-gamma and aldesleukin on the number, function, and activation state of immune effector-cells including T-cells and B-cells. •To perform detailed analyses of lymphocyte phenotypes and T-cell repertoires before and after idiotype-pulsed autologous dendritic cell vaccine APC8020. OUTLINE: Patients are stratified according to gender (male vs female) and prior treatment (post-chemotherapy vs post-peripheral blood stem cell transplantation). Patients are randomized to 1 of 2 arms. In both arms, patients undergo apheresis for collection of peripheral blood mononuclear cells for generation of dendritic cells (DC) on days 0, 14, and 28. APC8020 is generated by loading DC with immunoglobulin idiotype prepared from the patient's serum. •Arm I: Patients receive interferon-gamma subcutaneously (SC) once daily on days 1-5, 15-20, and 29-34 and idiotype-pulsed autologous dendritic cell vaccine APC8020 IV over 30-minutes on days 2, 16, and 30. •Arm II: Patients receive aldesleukin SC once daily days 1-5, 15-20, and 29-34 and idiotype-pulsed autologous dendritic cell vaccine APC8020 as in arm I. In both arms, treatment continues in the absence of disease progression. Peripheral blood samples are collected at baseline and on day 5 of courses 1 and 4 for cytokine immunomodulatory studies, including immunophenotyping for lymphocyte phenotypic markers (CD69, CD40L, CD25, CD30, CD71, CDW137, CD134, and HLADR) by flow cytometry and immunofluorescence; T-cell spectratyping by PCR and RT-PCR; T-cell proliferation to idiotype protein; and CTL and T-helper response by flow cytometry. After completion of study treatment, patients are followed every 3 months for 2 years and then every 6 months thereafter.</p>	
Completed	Vaccine Therapy in Treating Patients With High-Risk Stage III or Completely Resected Metastatic Melanoma	
	Conditions:	Stage IV Melanoma; Stage III Melanoma; Recurrent Melanoma
	Interventions:	Drug: dendritic cell-gp100-MART-1 antigen vaccine; Drug: sargramostim

	<p>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</p> <p>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.</p> <p>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.</p> <p>Patients are randomized to the following treatment arms:</p> <p>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.</p> <p>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.</p> <p>Patients are followed at 4 to 6 weeks.</p>							
Active, not recruiting	<table border="1"> <tr> <td colspan="2" data-bbox="264 648 1630 679">Vaccine Therapy and Celecoxib in Treating Patients With Metastatic Nasopharyngeal Cancer</td> <td data-bbox="1630 648 2143 763" rowspan="3"></td> </tr> <tr> <td data-bbox="264 679 436 709">Condition:</td> <td data-bbox="436 679 1630 709">Head and Neck Cancer</td> </tr> <tr> <td data-bbox="264 709 436 763">Interventions:</td> <td data-bbox="436 709 1630 763">Biological: Ad5F35-LMP1/LMP2-transduced autologous dendritic cells; Drug: celecoxib; Other: flow cytometry; Other: immunoenzyme technique; Other: laboratory biomarker analysis</td> </tr> </table>	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
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	<p>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. LMP¹ is a viral protein associated with Epstein-Barr virus.</p> <p>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.</p> <p>Secondary: •To evaluate the toxicities of this regimen in these patients.</p> <ul style="list-style-type: none"> •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. <p>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.</p> <p>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.</p> <p>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.</p> <p>After completion of study treatment, patients are followed monthly for up to 1 year.</p>					
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Melanoma</p> <table border="1" data-bbox="257 936 2123 1044"> <tr> <td data-bbox="257 936 432 967">Condition:</td> <td data-bbox="432 936 2123 967">Melanoma (Skin)</td> </tr> <tr> <td data-bbox="257 967 432 1044">Interventions:</td> <td data-bbox="432 967 2123 1044">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、</td> </tr> </table>		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、
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	<p>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</p> <p>OBJECTIVES:</p> <ul style="list-style-type: none"> •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. <p>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.</p> <p>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.</p> <p>PROJECTED ACCRUAL: A total of 30 patients will be accrued for this study within 1.5 years.</p>	
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
	<p>Primary Outcome Measures: •Immunological response to HPV, •Toxicity and safety of TA-HPV [Designated as safety issue: Yes]</p> <p>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]</p> <p>OBJECTIVES:</p> <ul style="list-style-type: none"> •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. <p>OUTLINE: This is an open-label, nonrandomized study.</p> <p>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.</p> <p>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.</p> <p>PROJECTED ACCRUAL: 44 patients will be entered over 1 year.</p>	
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

	<p>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.</p> <p>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.</p> <p>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</p> <p>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.</p> <p>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.</p> <p>PROJECTED ACCRUAL: A total of 50 patients (25 per arm) will be accrued for this study within 3 years</p>					
Active, not recruiting	<p>Vaccine Therapy With or Without Cyclophosphamide in Treating Patients Who Have Undergone Surgery for Stage II, Stage III, or</p> <table border="1" data-bbox="257 639 2123 759"> <tr> <td data-bbox="257 639 436 700">Condition:</td> <td data-bbox="436 639 2123 700">Melanoma (Skin)</td> </tr> <tr> <td data-bbox="257 700 436 759">Interventions:</td> <td data-bbox="436 700 2123 759">Biological: incomplete Freund's adjuvant; Biological: melanoma helper peptide vaccine; Biological: multi-epitope melanoma peptide vaccine; Biological: tetanus toxoid helper peptide; Drug: cyclophosphamide</td> </tr> </table>		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
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	<p>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.</p> <p>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.</p> <p>Primary:</p> <ul style="list-style-type: none"> •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. <p>Secondary:</p> <ul style="list-style-type: none"> •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. <p>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.</p> <ul style="list-style-type: none"> •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. <p>Treatment in all arms continues in the absence of disease progression or unacceptable toxicity.</p> <p>After completion of study treatment, patients are followed every 6 months for 2 years and then annually thereafter</p>	
Recruiting	<p>Anti-gp100 Cells Plus ALVAC gp100 Vaccine to Treat Advanced Melanoma</p> <p>Conditions: Metastatic Melanoma; Skin Cancer</p> <p>Interventions: Drug: cyclophosphamide; Drug: fludarabine phosphate</p>	

	<ul style="list-style-type: none"> •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. <p>Objectives: -To evaluate the safety and effectiveness of anti-gp100 cells and the ALVAC gp100 vaccine in treating patients with advanced melanoma.</p> <p>Eligibility: -Patients with metastatic melanoma for whom standard treatments have not been effective.</p> <p>Design: •Patients undergo scans, x-rays and other tests and leukapheresis to obtain white cells for laboratory treatment.</p> <ul style="list-style-type: none"> •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. <p>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</p>				
Active, not recruiting	<p>Safety and Immunogenicity of GlaxoSmithKline Biologicals' HPV Vaccine 580299 (Cervarix TM) in HIV Infected Females</p> <table border="1"> <tr> <td>Conditions:</td> <td>HPV-16/18 Infections; Cervical Neoplasia</td> </tr> <tr> <td>Interventions:</td> <td>Biological: Cervarix TM; Biological: Placebo Control</td> </tr> </table>	Conditions:	HPV-16/18 Infections; Cervical Neoplasia	Interventions:	Biological: Cervarix TM; Biological: Placebo Control
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Recruiting	<p>Immunization Against Tumor Cells in Sezary Syndrome</p> <table border="1"> <tr> <td>Conditions:</td> <td>Cutaneous T-Cell Lymphoma; Sezary Syndrome</td> </tr> <tr> <td>Intervention:</td> <td>Biological: Autologous Dendritic Cell Vaccine</td> </tr> </table>	Conditions:	Cutaneous T-Cell Lymphoma; Sezary Syndrome	Intervention:	Biological: Autologous Dendritic Cell Vaccine
Conditions:	Cutaneous T-Cell Lymphoma; Sezary Syndrome				
Intervention:	Biological: Autologous Dendritic Cell Vaccine				
	<p>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.</p> <p>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.</p> <p>Primary Outcome Measures: •Clinical response (clearance of skin lesions, clinical and radiographic improvement in lymphadenopathy)</p> <p>Secondary Outcome Measures: •Biological response, •Survival, •Activities of daily living, •Quality of Life</p> <p>Although the etiology of CTCL is not completely understood, immunologic factors appear to play an important role.</p> <p>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.</p> <p>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.</p>				
Completed	<p>Gene-Modified White Blood Cells Followed By Interleukin-2 and Vaccine Therapy in Treating Patients With Metastatic</p>				

	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	
	<p>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.</p> <p>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.</p> <p>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.</p> <p>Secondary: •Determine the in vivo survival of TCR gene-engineered cells in patients treated with this regimen.</p> <p>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*.</p> <p>NOTE: *Day 0 is 1-4 days after the last dose of fludarabine.</p> <p>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.</p> <p>Responding patients are followed at 1, 3, 6, and 12 months and then annually thereafter.</p> <p>PROJECTED ACCRUAL: A total of 61 patients will be accrued for this study.</p>	
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)	