

	<p>Detailed Description: To become eligible for therapy the following criteria must be fulfilled:                  No age or gender limit. /Patients with atypical malignant brain tumors. /Must have a Karnofsky performance of at least 60%. /Hematologic studies and chemistry profiles will be within the parameters of the protocol. /Tumor specimen of adequate size to yield protein concentration, tumor lysate peptide must be generated in sufficient quantity and patient must have no prior sensitivity to the components of the dendritic cell vaccine. /Patients are excluded if they have systemic disease, presence of acute infection, known history of autoimmune disorder and pregnancy.</p>	
Recruiting	<p><u>DC Vaccine Therapy Combined With Cytokine-Induced Killer Cell in Treating Patients With Renal Cell Carcinoma</u></p>	
	Condition:	Renal Cell Carcinoma/ in Patients With Renal Cell Cancer
	Interventions:	Biological: DC-CIK; Drug: IL-2/IFN- $\alpha$ Autologous Tumor Lysate (DC-Vaccine) 2009
	<p>Autologous Dendritic Cells Loaded With Autologous Tumor Lysate in Combination With Cytokine-Induced Killer Cell (CIK)</p>	
	<p>Primary Outcome: Objective tumor response (complete and partial response), Time to recurrence (TTR), Progression-free(PFS) and overall survival(OS) as measured by RECIST criteria. [ every 3 months ]                  Secondary Outcome: Immunity as measured by T-cell functionality (immuknow assay )to the tumor. Safety as measured by NCI common toxicity table (CTC) at completion of study. [ Time Frame: at screening, baseline, weeks 4 , 12 and years 1 after first vaccination, and at completion of study treatment ]                  Primary: Determine the clinical responses(objective response, progression-free survival, and overall survival) in patients with renal cell carcinoma treated with autologous dendritic cells (DC) loaded with autologous tumor lysate (DC vaccine) in combination with Cytokine-Induced Killer Cell (CIK).                  Secondary: Determine cellular immune response response in terms of immuknow assay, and correlate immune response with objective clinical response in patients treated with this regimen. Determine safety of multiple administrations of this regimens in these patients.</p>	
Recruiting	<p><u>One Dose of Cyclophosphamide or Denileukin Diftitox Followed By Expanding a Patient's Own T Cells in the Laboratory in Treating Patients With HER-2/Neu Overexpressing Metastatic Breast Cancer, Ovarian Cancer, or Non-Small Cell Lung Cancer Previously Treated With HER-2/Neu Vaccine</u></p>	
	Conditions:	HER2-positive Breast Cancer; Recurrent Breast Cancer; Recurrent Non-small Cell Lung Cancer; Recurrent Ovarian Epithelial Cancer; Recurrent Ovarian Germ Cell Tumor; Stage IV Breast Cancer; Stage IV Non-small Cell Lung Cancer; Stage IV Ovarian Epithelial Cancer; Stage IV Ovarian Germ Cell Tumor
	Interventions:	Drug: ex vivo-expanded HER2-specific T cells; Drug: cyclophosphamide; Biological: denileukin diftitox; Other: flow cytometry; Other: immunoenzyme technique 2005
	<p>Infusion of HER-2/Neu Specific T-cells in Patients With Advanced Stage HER-2/Neu Expressing Cancers Who Have Received a HER-2/Neu Vaccine</p>	

	<p>Primary Outcome: Feasibility of expanding HER2 specific T cells ex vivo [ Time Frame: From baseline ] /Safety [ Time Frame: From baseline ]</p> <p>Secondary Outcome: Extent to which to HER2 specific T cell immunity can be boosted. /Anti-tumor effects of HER2 specific T cells, as assessed by RECIST criteria. /Persistence of T cell immune augmentation[One month following last infusion and then every 2 months for 1 year ] /Progression.</p> <p>PRIMARY OBJECTIVES: I. To assess the feasibility of expanding HER2 specific T cells ex vivo for infusion into subjects who have advanced HER2 overexpressing cancer. II. To assess the toxicity associated with infusing autologous HER2 specific T cells into patients using either a single dose of cyclophosphamide or ONTAK (denileukin diftitox) prior to T cell infusion. SECONDARY OBJECTIVES: I. To investigate to what extent HER2 specific T cell immunity can be boosted in individuals treated with a single dose of cyclophosphamide or ONTAK (denileukin diftitox) followed by infusion of autologous HER2 specific T cells. II. To investigate the potential anti-tumor effects of HER2 specific T cells in patients with HER2 overexpressing advanced-stage cancers. III. To evaluate how long tumor antigen specific T cell immune augmentation persists in vivo after a single dose of cyclophosphamide or ONTAK (denileukin diftitox) followed by infusion of autologous HER2 specific T cells. OUTLINE: This is a dose-escalation study of ex vivo-expanded HER2-specific T cells. Patients are assigned to 1 of 2 treatment groups. GROUP A: Patients receive low-dose cyclophosphamide IV on day -1 and 3 escalating doses of autologous ex vivo-expanded HER2-specific T cells IV over 30 minutes on days 1, 10, and 20. GROUP B: Patients receive denileukin diftitox IV over 1 hour on day -1 and 3 escalating doses of autologous ex vivo-expanded HER2-specific T cells IV over 30 minutes on days 1, 10, and 20. After completion of study treatment, patients are followed periodically.</p>		
Not yet recruiting	<u>Human Papillomavirus (HPV) Vaccine Pilot Project</u>		
	Condition:	Cervical Cancer	
	Intervention:	Biological: Gardasil® HPV vaccine	
Recruiting	<u>Vaccine Therapy and Autologous Lymphocyte Infusion With or Without Fludarabine in Treating Patients With Metastatic</u>		MART-1/gp100/Tyrosinase/NY-ESO-1 Peptide-Pulsed Dendritic Cells Matured Using Cytokines With Autologous
	Conditions:	Intraocular Melanoma; Melanoma (Skin)	
	Interventions:	Biological: dendritic cell vaccine therapy; Biological: therapeutic autologous lymphocytes; Drug: fludarabine	

	<p>Primary Outcome: Overall survival. /Progression-free survival. Time to progression                  Secondary Outcome: Immunological response in patients receiving MART-1/gp100/tyrosinase/NY-ESO-1 with fludarabine. /Toxicity of MART-1/gp100/tyrosinase/NY-ESO-1 with fludarabine.                  Primary: Assess the toxicity and immune responses in HLA-A*0201-positive patients with chemotherapy-naïve metastatic melanoma treated with either escalating doses of fludarabine or no fludarabine followed by autologous lymphocyte infusion and vaccination with dendritic cells matured ex vivo with a cytokine cocktail and pulsed with MART-1/gp100/tyrosinase/NY-ESO-1/MAGE-3 class I and II peptides.                  Secondary: Compare clinical responses in patients receiving these regimens.                  All patients undergo two apheresis procedures, one to collect lymphocytes for the autologous lymphocyte infusion and one to collect dendritic cells (DC) for the production of the autologous vaccine. Autologous DC are pulsed with tumor antigen class I and II peptides derived from MART-1, gp100, tyrosinase, NY-ESO-1, and MAGE-3 and matured with a cytokine cocktail comprising tumor necrosis factor-<math>\alpha</math>, interleukin (IL)-6, IL-1<math>\beta</math>, and prostaglandin E2.                  Arm I: Patients receive fludarabine IV over 30 minutes on days -7 to -3 (beginning 3 days after the second apheresis procedure). Patients receive autologous lymphocyte infusion IV over 1 hour on day 0 followed by vaccination with autologous peptide-pulsed DC intranodally over 24 hours on days 1, 8, 22, and 36. Patients who have stable disease or who achieve a response to treatment may receive re-treatment with fludarabine, autologous lymphocyte infusion, and autologous peptide-pulsed DC vaccine (as above) approximately 4 weeks to 6 months after the last DC vaccine.                  Cohorts of 3-12 patients receive escalating doses of fludarabine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 6 or 3 of 12 patients experience dose-limiting toxicity.                  Arm II: Patients receive autologous lymphocyte infusion and vaccination with autologous peptide-pulsed DC as in arm I. Patients who have stable disease or who achieve a response to treatment may receive re-treatment with autologous lymphocyte infusion and autologous peptide-pulsed DC vaccine (as in arm I) approximately 4 weeks to 6 months after the last DC vaccine.                  After completion of study therapy, patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter.</p>						
Active, not recruiting	<p><u>Vaccine Therapy in Treating Patients With Liver or Lung Metastases From Colorectal Cancer</u></p> <table border="1" data-bbox="282 859 2114 979"> <tr> <td data-bbox="282 859 452 920">Conditions:</td> <td data-bbox="452 859 1630 920">Colorectal Cancer; Metastatic Cancer</td> <td data-bbox="1630 859 2114 979" rowspan="2">Active Immunotherapy With PANVAC or Autologous, Cultured Dendritic Cells Infected With PANVAC After Complete Resection of Hepatic or Pulmonary Metastases of Colorectal Carcinoma</td> </tr> <tr> <td data-bbox="282 920 452 979">Interventions:</td> <td data-bbox="452 920 1630 979">Biological: falimarev; Biological: inalimarev; Biological: sargramostim; Biological: therapeutic autologous dendritic cells 2005</td> </tr> </table>		Conditions:	Colorectal Cancer; Metastatic Cancer	Active Immunotherapy With PANVAC or Autologous, Cultured Dendritic Cells Infected With PANVAC After Complete Resection of Hepatic or Pulmonary Metastases of Colorectal Carcinoma	Interventions:	Biological: falimarev; Biological: inalimarev; Biological: sargramostim; Biological: therapeutic autologous dendritic cells 2005
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Interventions:	Biological: falimarev; Biological: inalimarev; Biological: sargramostim; Biological: therapeutic autologous dendritic cells 2005						
	<p>Primary Outcome: •Disease-free survival at 2 years                  Secondary Outcome: •Rate of immune response as measured by ELISpot assay at 16 weeks                  Primary: •Compare 2-year disease-free survival of patients with completely resected hepatic or pulmonary metastases secondary to colorectal cancer treated with adjuvant vaccine therapy comprising vaccinia-CEA-MUC-1-TRICOM vaccine (PANVAC-V) and fowlpox-CEA-MUC-1-TRICOM vaccine (PANVAC-F) administered with autologous dendritic cells or with sargramostim (GM-CSF).                  Secondary: •Compare the rate and magnitude of immune response, as determined by ELISpot, in patients treated with these regimens.                  OUTLINE: This is a randomized study. Patients are randomized to 1 of 2 treatment arms.                  •Arm I: Patients undergo leukapheresis to obtain leukocytes for generation of autologous dendritic cells (DC). Patients then receive autologous DC loaded with vaccinia-CEA-MUC-1-TRICOM (PANVAC-V) vaccine subcutaneously (SC) and intradermally (ID) on day 1 and autologous DC loaded with fowlpox-CEA-MUC-1-TRICOM (PANVAC-F) vaccine SC and ID on days 28, 56, and 84.                  •Arm II: Patients receive PANVAC-V SC on day 1 and PANVAC-F SC on days 28, 56, and 84. Patients also receive sargramostim (GM-CSF) SC into the same injection site once daily on days 0-3, 28-31, 56-59, and 84-87. After completion of study treatment, patients are followed for 2 years.</p>						

Terminated	<u>Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Colorectal Cancer</u>		Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 in Combination With Tegafur/Uracil/ Folate in Treating Patients With Refractory Colorectal Cancer
	Conditions:	Colorectal Cancer; Colon Cancer; Rectal Cancer	
	Intervention:	Biological: VEGFR1 and VEGFR2 2008	
<p>Primary Outcome: •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [ 2 months ]</p> <p>Secondary Outcome: •To evaluate immunological responses [ 2 months ]</p> <p>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, clinical and immunological response of those peptides. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. The patients will also receive oral chemotherapy (Tegafur/Uracil/Folate) simultaneously. Repeated cycles of the vaccine and the chemotherapy will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine.</p>			
Terminated	<u>Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Colorectal Cancer</u>		Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*2402 in Combination With Tegafur/Uracil/ Folate in Treating Patients With Refractory Colorectal Cancer
	Conditions:	Colorectal Cancer; Colon Cancer; Rectal Cancer	
	Intervention:	Biological: RNF43, TOMM34, VEGFR1 and VEGFR2 2008	
<p>Primary Outcome: •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [2 months ]</p> <p>Secondary Outcome: •To evaluate immunological responses [ 2 months ]</p> <p>RNF43 and TOMM34 have been identified as cancer specific molecules especially in colorectal cancer using genome-wide expression profile analysis by cDNA microarray technique. 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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, RNF43 peptide (1mg), TOMM34 peptide (1mg), VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. The patients will also receive oral chemotherapy (Tegafur/Uracil/Folate) simultaneously. Repeated cycles of the vaccine and the chemotherapy will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>			
Not yet recruiting	<u>Does the HPV Vaccine Cause the Same Response in Adolescent Kidney and Liver Transplant Patients as in Healthy Controls?</u>		Immunogenicity Of A Prophylactic Quadrivalent Human Papillomavirus (Types 6, 11, 16, And 18) L1 Virus-Like Particle Vaccine In Male And Female Adolescent Transplant Recipients.
	Conditions:	Cervical Cancer; HPV; Warts	
	Intervention:	Biological: Quadrivalent HPV for types 6, 11, 16 and 18 2010	
The purpose of the study is to understand if children with liver and kidney transplants develop the antibodies from the Gardasil vaccine.			
Completed	<u>Peptide-pulsed vs. RNA-transfected Dendritic Cell Vaccines in Melanoma Patients</u>		DC Vaccines Presenting HLA Class I and II Restricted Tumor Epitopes Either by Peptide-pulsing or mRNA Transfection in Melanoma Patients
	Condition:	Melanoma Stage III or IV	
	Intervention:	Biological: autologous dendritic cell vaccine 2005	

	<p>Primary Outcome: •Immune response [first 10 years ] Secondary Outcome: •Safety [first 10 years ]</p> <p>MHC Class I restricted epitopes: Active Comparator: HLA-A2.1 patients are vaccinated with dendritic cells loaded with MHC Class I restricted epitopes of tumor antigens gp100 and tyrosinase. /Intervention: Biological: autologous dendritic cell vaccine.</p> <p>MHC Class I and II restricted epitopes: Experimental: HLA-A2.1 and HLA-DR4 patients are vaccinated with dendritic cells loaded with MHC Class I and II restricted epitopes of tumor antigens gp100 and tyrosinase. Intervention: Biological: autologous dendritic cell vaccine</p> <p>mRNA transfected DC: Experimental: HLA-A2.1 and/or HLA-DR4 patients are vaccinated with dendritic cells transfected with mRNA encoding tumor antigens gp100 and tyrosinase. Intervention: Biological: autologous dendritic cell vaccine</p>					
Terminated	<p><u>Vaccine Therapy in Treating Patients With Acute Myeloid Leukemia</u></p> <table border="1"> <tr> <td>Condition:</td> <td>Leukemia</td> </tr> <tr> <td>Interventions:</td> <td>Drug: autologous tumor cell vaccine; Drug: therapeutic autologous dendritic cells; Procedure: tumor cell-derivative vaccine therapy 2005</td> </tr> </table>		Condition:	Leukemia	Interventions:	Drug: autologous tumor cell vaccine; Drug: therapeutic autologous dendritic cells; Procedure: tumor cell-derivative vaccine therapy 2005
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Interventions:	Drug: autologous tumor cell vaccine; Drug: therapeutic autologous dendritic cells; Procedure: tumor cell-derivative vaccine therapy 2005					
	<p>Dendritic/Leukemic Fusion Cell Vaccine Therapy For AML Patients In First Remission; A Phase I Clinical Trial</p>					
	<p>Primary: •Determine the maximum tolerated dose of autologous dendritic and leukemic fusion cell vaccine in patients with acute myeloid leukemia. •Determine the toxicity of this vaccine in these patients.</p> <p>Secondary: •Determine whether cellular immunity can be induced by this vaccine in these patients</p> <p>Cohorts of 3 patients receive escalating doses of autologous dendritic and leukemic fusion cell vaccine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 3 patients experience dose-limiting toxicity. Patients are followed every 3 months for 5 years.</p>					
Completed	<p><u>Vaccine Therapy in Treating Patients With Metastatic Melanoma</u></p> <table border="1"> <tr> <td>Condition:</td> <td>Melanoma (Skin)</td> </tr> <tr> <td>Intervention:</td> <td>Biological: recombinant fowlpox-TRICOM vaccine</td> </tr> </table>		Condition:	Melanoma (Skin)	Intervention:	Biological: recombinant fowlpox-TRICOM vaccine
Condition:	Melanoma (Skin)					
Intervention:	Biological: recombinant fowlpox-TRICOM vaccine					
	<p>Intratumoral Injection of rF-TRICOMTM in Patients With Metastatic Melanoma Who Have Detectable Tumor Associated T Cells</p>					
	<p>Primary Outcome: •Safety and tolerability. /•Local response rate (complete or partial response, stable or progressive disease). /•Overall clinical response as measured by RECIST criteria.</p> <p>Secondary Outcome: •Change in mRNA expression of B7-1, LFA-3, and/or ICAM-1 in the tumor microenvironment and correlate with response. /•Change in tumor-associated T cells and correlate with response. /•Time to tumor progression.</p> <p>Primary: •Determine the safety and tolerability of intratumoral fowlpox-TRICOM in patients with metastatic melanoma. /•Determine the local response rate in patients treated with this agent. /•Determine systemic clinical response in patients treated with this agent.</p> <p>Secondary: •Determine the increase in transgene expression of B7-1, leukocyte function-associated antigen-3 (LFA-3), and intercellular adhesion molecule-1 (ICAM-1) in patients treated with this agent. /•Determine the effects of this agent on CD8-positive antitumor T-cell frequency as measured by tetramer and ELISpot in patients who are HLA-A2 positive. /•Correlate transgene expression of B7-1, LFA-3, and ICAM-1 by tumor cells with changes in function or number of melanoma antigen-specific CD8-positive T lymphocytes in patients treated with this agent.</p> <p>Patients are followed every 3 months until disease progression and then approximately every 6 months for 5-15 years</p>					
Terminated	<p><u>Study of a Multi-Antigen Therapeutic Vaccine in Patients With Metastatic Melanoma</u></p> <table border="1"> <tr> <td>Conditions:</td> <td>Melanoma; Cancer 2008</td> </tr> <tr> <td>Interventions:</td> <td>Biological: ALVAC(2) Melanoma multi-antigen therapeutic vaccine; Biological: Intron A, Interferon alpha -2b</td> </tr> </table>		Conditions:	Melanoma; Cancer 2008	Interventions:	Biological: ALVAC(2) Melanoma multi-antigen therapeutic vaccine; Biological: Intron A, Interferon alpha -2b
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Interventions:	Biological: ALVAC(2) Melanoma multi-antigen therapeutic vaccine; Biological: Intron A, Interferon alpha -2b					
Has Results	<p>Multi-Antigen Therapeutic Vaccine in Patients With Metastatic Melanoma</p>					

	<p><b>Primary Outcome:</b> •Summary of Disease Progression in Study Participants, Intent-to-treat Population [up to 35 weeks]. /Number of evaluable study participants who had died or experienced objective disease progression (no clinical objective response to treatment as evaluated by computed tomography [CT] scans or physical examination). /•Progression-Free Survival Time by Response Evaluation Criteria in Solid Tumor (RECIST) Criteria in the Intent-to-treat Population [up to 35 weeks]. /Progression-Free Survival was assessed by the Response Evaluation Criteria in Solid Tumor criteria from the computed tomography (CT) scans, as per-protocol</p> <p><b>Secondary Outcome:</b> •Best Overall Objective Response as Number of Participants Responding in the Intent-to-treat Population [up to 35 weeks]. /Objective response rate (ORR) is the sum of complete response (CR) and partial response (PR) Complete response = Disappearance of all target lesions. Partial response = At least a 30% decrease in the sum of longest diameter of target lesions, taking as reference the baseline sum longest diameter. /•Best Overall Objective Response in the Intent-to-treat Population [up to 35 weeks]. /Objective response rate (ORR) is the sum of complete response (CR) and partial response (PR) Complete response = Disappearance of all target lesions. Partial response = At least a 30% decrease in the sum of longest diameter of target lesions, taking as reference the baseline sum longest diameter. /•Best Overall Objective Response as Mean Duration of Response (Weeks) in the Intent-to-treat Population [up to 35 weeks]. /Objective response rate (ORR) is the sum of complete response (CR) and partial response (PR) Complete response = Disappearance of all target lesions. Partial response = At least a 30% decrease in the sum of longest diameter of target lesions, taking as reference the baseline sum longest diameter.</p> <p>•Number of Participants Reporting a Grade 3 or Grade 4 Adverse Events by Preferred Term [up to 35 weeks]. /Common Terminology Criteria for Adverse Events (CTCAE) definitions: Grade 3 is a severe adverse event; Grade 4 is a life-threatening or disabling adverse event.</p>	
Terminated	<p><u>Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Breast Cancer</u></p> <p>Condition: Breast Cancer</p> <p>Intervention: Biological: VEGFR1 and VEGFR2 2008</p>	<p>Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201for Refractory Breast Cancer</p>
	<p><b>Primary Outcome:</b> •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [ 2 months ]</p> <p><b>Secondary Outcome:</b> •To evaluate immunological responses [2 months]</p> <p>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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of the vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>	
Recruiting	<p><u>Radiation, Chemotherapy, Vaccine and Anti-MART-1 and Anti-gp100 Cells for Patients With Metastatic Melanoma</u></p> <p>Conditions: Melanoma; Skin Cancer</p> <p>Interventions: Drug: MART-1: 26-35(27L) Peptide; Drug: Montanide ISA 51 VG; Drug: gp100:154-162 Peptide; Drug: PG 13/Faf2aB C 162D1 (anti- MART-1 F5 TCR); Drug: PG13-154-EcII AIB (anti-gp100:154-162 TCR); Procedure: Radiation; Drug: Aldesleukin; Drug: Fludarabine; Drug: Cyclophosphamide; Genetic: Anti-gp 100:154 TCR PBL; Genetic: Anti-MART-1 F5 TCR PBL 2009</p>	<p>Metastatic Melanoma Using a Chemoradiation Lymphodepleting Conditioning Regimen Followed by Infusion of Anti-Mart-1 and Anti-gp100 TCR-Gene Engineered Lymphocytes and Peptide Vaccines</p>
	<p>•The procedure also uses one of two vaccines-the anti-MART-1 peptide or the anti-gp100 peptide-to stimulate cells in the immune system that may increase the effectiveness of the anti-MART-1 and anti-gp100 cells. Both vaccines are made from a virus that is modified to carry a copy of the MART-1 gene or gp100 gene. The virus cannot cause disease in humans.</p> <p><b>Primary Outcome:</b> •Patients with melanoma, determine if the anti-gp100:154-162 TCR and anti-MART-1:27-25 TCR PBLs, IL-2 and the gp100:154-162 or the MART-1:26-35(27L) peptides after chemoradiation will lead to complete tumor regression and increased cell persisten...</p> <p><b>Secondary Outcome:</b> •Determine the toxicity profile of these treatment regimen</p>	

Completed	<u>Broad Spectrum HPV Vaccine Dose Escalation Study</u>		Dose-Escalation Study of Octavalent Human Papillomavirus (HPV) L1 Virus-Like Particle (VLP) Vaccine Adjuvanted With Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS) and ISCOMATRIX™ (IMX)
	Conditions:	Human Papilloma Virus; Cervical Cancer; Vulvar Cancer; Vaginal Cancer; Genital Warts	
	Interventions:	Biological: V502; Biological: Comparator: V502 Dose formulation 2; Biological: Comparator: V502 Dose formulation 3; Biological: Comparator: V502 Dose formulation 4; Biological: Comparator: Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine (GARDASIL™) 2009	
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Unresected Stage III or Stage IV Melanoma</u>		Vaccines from white blood cells and a donor's tumor cells may help the body build an effective immune response to kill tumor
	Condition:	Melanoma (Skin) Matured Dendritic Cells Pulsed Ex Vivo With 3 Melanoma Cell Line Lysates (IDD-3)	
	Intervention:	Biological: autologous dendritic cell-allogeneic melanoma tumor cell lysate vaccine 2005	
	<p><b>Primary Outcome:</b> •Tumor control rate (complete response, partial response, or stable disease) for 4-8 weeks</p> <p><b>Secondary Outcome:</b> •Safety and •Immune response</p> <p>Primary: •Determine the clinical activity of vaccine therapy comprising autologous dendritic cells pulsed with allogeneic melanoma tumor cell lysates (IDD-3), as measured by tumor control, in patients with unresected stage IIIB or IIIC or stage IV melanoma.</p> <p>Secondary: •Determine the immunologic activity of this vaccine, as measured by T-cell and antibody responses to lysate or to melanoma antigens or peptides, in these patients. •Determine the safety of this vaccine, as measured by the incidence and severity of adverse events, in these patients.</p> <p>patients are followed at 2, 10, 18, and 26 weeks</p>		
Active, not recruiting	<u>Aldesleukin With or Without Vaccine Therapy in Treating Patients With Stage IV Melanoma</u>		IL-2 With or Without an Allogeneic Large Multivalent Immunogen (LMI) Vaccine for the Treatment of Stage IV Melanoma
	Condition:	Stage IV Melanoma	
	Interventions:	Biological: aldesleukin; Biological: allogeneic large multivalent immunogen vaccine 2008	
	<p>Aldesleukin may stimulate the white blood cells to kill tumor cells. Vaccines may help the body build an effective immune response to kill tumor cells. Giving aldesleukin together with vaccine therapy may kill more tumor cells. It is not yet known whether aldesleukin is more effective with or without vaccine therapy in treating melanoma.</p> <p><b>Primary Outcome:</b> •Progression-free survival [ at 2 months ]. /To determine progression free survival (PFS) of LMI vaccination plus IL-2, IL-2 alone, and crossover. Progression free survival will be measured in months from time of response to time of disease progression as defined by Solid Tumor Response Criteria (RECIST).</p> <p><b>Secondary Outcome:</b> •Clinical response [ 2 months ]. /To determine clinical response of each treatment group - Clinical response will be determined using Solid Tumor Response Criteria (RECIST). /•Survival [1 Year, 2 Years ]. /To determine one and two year survival rates of each treatment group. /•Immune response [48 hours ]. /Immune responses will be assessed by Delayed Type Hypersensitive (DTH) responses to LMI, IFN-γ production by CD8 T cells using the ELISPOT assay, and CD8 T cell binding to HLA-A2 multimers complexed with melanoma-derived peptides (pentamer analysis). DTH reactions are determined at 48 hours by measuring the largest diameter and right angle diameter of the area of induration and calculating the mean. DTH responses are recorded as present or absent but cannot be used as a quantitative measure of immune activation.</p> <p>Patients undergo blood sample collection periodically for correlative laboratory studies. Samples are analyzed for immune responses to keyhole limpet hemocyanin and tetanus toxoid (control antigens) by ELISA assay; IFN-γ production by CD8 T cells in response to melanoma-derived peptides by ELISpot assay; delayed-type hypersensitivity response to vaccination; and frequency of peripheral blood lymphocytes, including T cells, B cells, NK cells, and monocytes, by flow cytometry.</p>		
Completed	<u>Active Specific Immunotherapy for Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype Antigen Vaccines</u>		Immunotherapy for Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype Antigen Vaccines
	Conditions:	B Cell Lymphoma; Follicular Lymphoma; Lymphoma	
	Interventions:	Drug: Id-KLH Vaccine; Drug: GM-CSF 1999	

	<p>The idiotype of the immunoglobulin on a given B cell malignancy (Id) can serve as a clonal marker, and a previous pilot study in lymphoma patients has demonstrated that autologous Id protein can be formulated into an immunogenic, tumor specific antigen by conjugation to a carrier protein (KLH) and administration with an emulsion-based adjuvant. The goals of vaccine development in the current study are to develop vaccines: 1) with improved potency and 2) which are more effective at inducing cell-mediated immune responses. The selection of GM-CSF as the immunological "adjuvant" is a direct extension of our laboratory studies in small animal models demonstrating that GM-CSF can enhance the potency of the prototype Id-KLH vaccine by augmenting almost exclusively the cellular arm of the immune response.</p>	
Recruiting	<p><u>Monoclonal Antibody Therapy and Vaccine Therapy in Treating Patients With Stage IV Melanoma That Has Been Removed By</u></p> <p>Condition: Melanoma (Skin)</p> <p>Interventions: Biological: MART-1:26-35(27L) peptide vaccine; Biological: NY-ESO-1 peptide vaccine; Biological: anti-PD-1 human monoclonal antibody MDX-1106; Biological: gp100:209-217(210M) peptide vaccine; Biological: gp100:280-288(288V) peptide vaccine; Drug: Montanide ISA 51 VG; Other: laboratory biomarker analysis; Other: pharmacological study 2010</p>	<p>This phase I trial is studying the side effects and best dose of anti-PD-1 human monoclonal antibody MDX-1106 when given together with and vaccine therapy in treating patients with stage IV melanoma that has been removed by surgery</p>
	<p>Primary: •To assess the safety and tolerability of treatment with anti-PD-1 human monoclonal antibody MDX-1106 in combination with a peptide vaccine comprising gp100:209-217(210M) peptide, MART-1:26-35(27L) peptide, gp100:280-288(288V) peptide, NY-ESO-1 peptide, and Montanide ISA 51 VG in patients with HLA-A*0201-positive, resected stage IV melanoma.                  Secondary: •To evaluate the immune response to this treatment at week 12 compared to the immune response to treatment with the peptide vaccine alone that was determined in previous studies. /To assess the host immune response (immunogenicity) to anti-PD-1 human monoclonal antibody MDX-1106. /•To assess, preliminarily, the efficacy of this treatment as measured as time to relapse. Patients are followed up for up to 2 years.                  RATIONALE: Monoclonal antibodies, such as anti-PD-1 human monoclonal antibody MDX-1106, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Vaccines made from peptides may help the body build an effective immune response to kill tumor cells. Giving monoclonal antibody therapy together with vaccine therapy may be an effective treatment for</p>	
Completed	<p><u>Vaccine Treatment for Advanced Malignant Melanoma</u></p> <p>Condition: Malignant Melanoma</p> <p>Intervention: Biological: HyperAcute-Melanoma Vaccine 2006</p>	<p>Antitumor Vaccination Using Alpha(1,3)Galactosyltransferase Expressing Allogeneic Tumor Cells for Refractory or Recurrent Malignant Melanoma</p>



	<p><b>Primary Outcome:</b> •Number of Subjects Who Seroconverted for Anti-human Papilloma Virus 16 (Anti-HPV-16) and Anti-human Papilloma Virus 18 (Anti-HPV-18) Antibodies [ Month 7 ]. /Seroconversion is defined as the appearance of antibodies with titers greater than or equal to the predefined cut-off value in the serum of subjects seronegative before vaccination. Cut-off values assessed include 8 enzyme-linked immunosorbent assay units per milliliter (EL.U/mL) for anti-HPV-16 antibodies and 7 EL.U/mL for anti-HPV-18 antibodies.</p> <p><b>Secondary Outcome:</b> •Titers of Anti-human Papilloma Virus 16 (Anti-HPV-16) and Anti-human Papilloma Virus 18 (Anti-HPV-18) Antibodies [Month 7 ]. /Titers are given as Geometric Mean Titers (GMTs) expressed as Enzyme-linked Immunosorbent Assay Units Per Milliliter (EL.U/mL).</p> <p>•Number of Subjects Reporting Solicited Symptoms [ 7 days ]. /Solicited local symptoms assessed include pain, redness and swelling. Solicited general symptoms assessed include arthralgia, fatigue, fever, gastro-intestinal symptoms, headache, myalgia, rash and urticaria.</p> <p>•Number of Subjects Reporting Unsolicited Adverse Events (AEs) [ Within 30 days]. /Unsolicited adverse event = Any adverse event (AE) reported in addition to those solicited during the clinical study. Also any "solicited" symptom with onset outside the specified period of follow-up for solicited symptoms was reported as an unsolicited adverse event.</p> <p>•Number of Subjects Reporting Unsolicited Adverse Events as New Onset Chronic Diseases (NOCs) and Other Medically Significant Adverse Events (AEs) [ (up to Month 7) ]. /NOCs assessed include e.g. autoimmune disorders, asthma, type I diabetes, allergies,...</p> <p>Medically significant AEs assessed include AEs prompting emergency room or physician visits that are not related to common diseases or routine visits for physical examination or vaccination, or SAEs that are not related to common diseases.</p> <p>•Number of Subjects Reporting Serious Adverse Events [ (up to Month 7) ]. /Serious adverse events assessed include medical occurrences that results in death, is life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subject.</p>		
Completed	<p><u>Study to Evaluate the Immune Response and Safety of GSK Biologicals' HPV Vaccine in Healthy Women Aged 18-35 Years</u></p>		<p>to Evaluate the Immunogenicity &amp; Safety of GSK Biologicals' HPV-16/18 L1 VLP AS04 Vaccine</p>
Has Results	<p>Conditions: Human Papillomavirus (HPV) Infection; Associated Cervical Neoplasia</p> <p>Interventions: Biological: Placebo; Biological: HPV-16/18 L1 VLP AS04 (Cervarix TM)</p>		
Completed	<p><u>Vaccine Therapy in Treating Patients With Advanced Melanoma</u></p> <p>Conditions: Intraocular Melanoma; Malignant Conjunctival Neoplasm; Melanoma (Skin)</p> <p>Interventions: Biological: incomplete Freund's adjuvant; Biological: multi-epitope melanoma peptide vaccine; Biological: tetanus toxoid helper peptide; Procedure: biopsy 2008</p>		<p>Multipeptide Vaccine in Melanoma Patients With Evaluation of the Injection Site Microenvironment</p>
	<p><b>Primary Outcome:</b> •Features of lymphoid neogenesis at the replicate immunization site.</p> <p><b>Secondary Outcome:</b> •Proliferating T cells in the replicate immunization site. /•Toll-like receptor signaling in the replicate immunization site. /</p> <p>•Regulatory processes in the replicate immunization sites. /•CD8+ and CD4+ peptide-reactive T-cell responses among lymphocytes infiltrating skin at the replicate immunization sites and in the peripheral blood. /•CCR and integrin expression on vaccine-induced T cells in the peripheral blood and at the replicate immunization site.</p>		
Recruiting	<p><u>Dendritic Cell Based Therapy for Breast Cancer Patients</u></p> <p>Condition: Breast Cancer</p> <p>Interventions: Biological: DC vaccine; Drug: Exemestane 2009</p>		<p>p53peptide-pulsed Dendritic Cells in Combination With Second Line Endocrine Therapy (Exemestane, Aromasin®) as Treatment for Breast Cancer</p>
	<p><b>Primary Outcome:</b> •To determine time to progression [ after 8 and 16 weeks ] <b>Secondary Outcome:</b> •To evaluate safety of DC vaccination in combination with Exemestane, to evaluate clinical tumor response, to evaluate treatment induced immune response to p53 end to evaluate duration of tumor and immune responses [Weekly the first 4 weeks, thereafter biweekly for five months, thereafter monthly ]</p> <p>Detailed Description: Only patients who have tumors &gt; 5 % positive for p53 by IHC can be referred to this treatment. All patients will receive standard dosage of Exemestane +/- p53-DC vaccination. Patients who express HLA-A2 will also receive DC vaccination. Patients that do not express HLA-A2 will receive only Exemestane and be regarded as controls.</p>		

Completed	Evaluation of the Immune and Safety Response of GlaxoSmithKline (GSK) Biologicals' HPV Vaccine in Healthy Indian Women		
Has Results	Conditions:	Cervical Cancer; Papillomavirus Infection	
	Interventions:	Biological: HPV-16/18 VLP/AS04 Vaccine (Cervarix TM); Biological: Placebo 2009	
Active, not recruiting	Chemotherapy, Radiation Therapy, and Vaccine Therapy With Basiliximab in Treating Patients With Glioblastoma Multiforme That Has Been Removed by Surgery		Primary: Functional suppressive capacity of CD4+CD25+CD127- T-regulatory cells. / Comparison of proliferative T-cell response to PHA among treatment groups
	Condition:	Brain and Central Nervous System Tumors	
	Interventions:	Biological: PEP-3-KLH conjugate vaccine; Biological: daclizumab; Drug: temozolomide; Other: placebo; Biological: PEP-3-KLH (with versus without daclizumab/basiliximab) [26 months ] 2008	
	<p><b>Primary:</b> •To determine if basiliximab inhibits the functional and numeric recovery of T-regulatory cells (Tregs) after therapeutic temozolomide (TMZ)-induced lymphopenia in the context of vaccinating adult patients with newly diagnosed glioblastoma multiforme (GBM) using PEPvIII-keyhole limpet hemocyanin (KLH).  <b>Secondary:</b> •To evaluate the safety of basiliximab in the context of vaccinating adult patients with newly diagnosed GBM using PEP-3-KLH conjugate vaccine during recovery from therapeutic TMZ-induced lymphopenia. /•To determine if basiliximab enhances the magnitude or character of PEPvIII-KLH-induced cellular or humoral immune responses, inhibits or enhances activation-induced cell death, or induces immunologic or clinical evidence of autoimmunity. /•To determine if basiliximab enhances the magnitude or character of PEPvIII-KLH-induced cellular or humoral immune responses, inhibits or enhances activation-induced cell death, or induces immunologic or clinical evidence of autoimmunity. /•To determine if basiliximab alters the phenotype (CD56-expression), cytokine secretion profile, or cytotoxicity of CD3-negative CD56-positive natural killer cells. /•To determine if basiliximab, in addition to vaccination, extend progression-free survival compared to historical cohorts. /•To characterize immunologic cell infiltrate in recurrent tumors and seek evidence of antigen escape outgrowth.</p> <p>RATIONALE: Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Radiation therapy uses high-energy x-rays to kill tumor cells. Vaccines may help the body build an effective immune response to kill tumor cells. Monoclonal antibodies, such as basiliximab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. It is not yet known whether giving chemotherapy, radiation therapy, and vaccine therapy together with basiliximab is a more effective treatment for glioblastoma multiforme than chemotherapy, radiation therapy, and vaccine therapy alone.</p>		
Active, not recruiting	Rituximab, Autologous Vaccine Therapy, and Sargramostim in Treating Patients With Recurrent or Refractory Follicular B-Cell		Rituxan Plus FavId (Tumor-Specific Idiotypic-KLH) and GM-CSF Immunotherapy in Patients With Grade 1 or 2 Follicular B-Cell Lymphoma
	Condition:	Lymphoma	
	Interventions:	Biological: autologous immunoglobulin idiotype-KLH conjugate vaccine; Biological: rituximab; Biological: sargramostim 2003	
	<p><b>OBJECTIVES:</b> •Compare the 9-month objective response rate of patients with recurrent or refractory grade I or II follicular B-cell lymphoma treated with rituximab, autologous immunoglobulin idiotype-KLH conjugate vaccine, and sargramostim (GM-CSF) vs historical control patients who received rituximab alone./•Compare the median duration of response and median time to progression in patients treated with this regimen vs historical controls. /•Determine the immune response (humoral and/or cellular) of patients treated with this regimen. /•Determine the safety of this regimen in these patients.</p> <p>Patients are followed every 6 months for at least 2 years. RATIONALE: Monoclonal antibodies such as rituximab can locate cancer cells and either kill them or deliver cancer-killing substances to them without harming normal cells. Vaccines made from a person's cancer cells may make the body build an immune response to kill cancer cells. Colony-stimulating factors such as sargramostim increase the number of immune cells found in bone marrow or peripheral blood. Combining rituximab with autologous vaccine therapy and sargramostim may cause a stronger immune response and kill more cancer cells.</p>		
Active, not recruiting	Vaccine Therapy in Treating Patients With Acute Lymphoblastic Leukemia		Vaccination With Autologous CD40-

recruiting	Condition:	Leukemia	Activated Acute Lymphoblastic Leukemia Cells
	Intervention:	Biological: autologous tumor cell vaccine 2001	
<p><b>OBJECTIVES:</b> •Determine the feasibility of generating a vaccine comprising CD40-activated autologous leukemic cells for patients with B-cell acute lymphoblastic leukemia (ALL). /•Determine the feasibility of this regimen in patients with B-cell ALL. /•Determine the toxicity of this regimen in these patients. /•Assess the ALL-specific immunity in patients treated with this regimen. /•Assess the generation of immunity to control antigens in patients treated with this regimen. /•Determine, in a preliminary manner, the effect of this regimen on tumor response in these patients. Patients are followed at approximately 2 months after last vaccination.</p>			
Active, not recruiting	Vaccine Therapy Followed by Biological Therapy in Treating Patients With Stage III or Stage IV Melanoma		a MART-1/gp100/Tyrosinase Peptide-Pulsed Dendritic Cell Vaccine Treated With CD40 Ligand/Gamma Interferon With Subcutaneous IL-2 for Metastatic Melanoma
	Condition:	Melanoma (Skin)	
	Interventions:	Biological: MART-1 antigen; Biological: aldesleukin; Biological: gp100 antigen; Biological: recombinant CD40-ligand; Biological: recombinant interferon gamma; Biological: recombinant interleukin-4; Biological: sargramostim; Biological: therapeutic autologous dendritic cells; Biological: therapeutic tumor infiltrating lymphocytes; Biological: tyrosinase peptide; Radiation: Candida albicans skin test reagent	
<p><b>OBJECTIVES:</b> •Determine the clinical response rate and immune response in HLA-A2 positive patients with stage III or IV melanoma after receiving autologous dendritic cells pulsed with melanoma antigen peptides (MART-1:26-35, gp100:209-217, and tyrosinase:368-376) and treated ex vivo with CD40-ligand and interferon gamma, followed by interleukin-2 in vivo. /•Determine the toxicities of this regimen in these patients. Patients are followed at 4 weeks, then every 3 months for 2 years, then every 6 months for 3 years, and then annually thereafter.</p> <p><b>RATIONALE:</b> Vaccines made from melanoma cells may make the body build an immune response to kill tumor cells. Biological therapies such as interferon gamma and interleukin-2 use different ways to stimulate the immune system and stop cancer cells from growing. Combining vaccine therapy with biological therapy may kill more tumor cells.</p>			
Completed	A Study to Evaluate Tolerability and Immunogenicity of V504 Administered Concomitantly With GARDASIL		
	Conditions:	Cervical Cancer; Vulvar Cancer; Vaginal Cancer; Genital Warts; Human Papillomavirus Infection	
	Interventions:	Biological: V504; Biological: Comparator: Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine; Biological: Comparator: Placebo (unspecified)	
Completed	Vaccine Therapy Plus Interleukin-2 in Treating Patients With Stage III, Stage IV, or Recurrent Follicular Lymphoma		Immunotherapy for Follicular Lymphomas With Liposomes Containing Tumor-Derived Antigen and IL-2
	Condition:	Lymphoma	
	Interventions:	Biological: aldesleukin; Biological: autologous tumor cell vaccine 2001	
<p><b>OBJECTIVES:</b> •Assess the safety of immunotherapy with autologous tumor cell vaccine and interleukin-2 in patients with stage III, IV, or recurrent follicular lymphoma. /•Determine the clinical response of patients treated with this regimen. /•Assess the immune response of patients treated with this vaccine.</p> <p><b>OUTLINE:</b> This is a multicenter study. Patients are stratified according to prior therapy (no prior biologic therapy or chemotherapy for lymphoma vs prior prednisone, doxorubicin, cyclophosphamide, and etoposide (PACE) chemotherapy). Patients without prior therapy are further stratified according to accessibility of lymph nodes (easily accessible (stratum Ia) vs not easily accessible (stratum Ib)). Patients are followed at 1 and 4 months, every 3 months for 1 year, and every 6 months thereafter until relapse or progression of disease.</p>			
Active, not recruiting	Vaccine Therapy in Treating Patients With Newly Diagnosed Glioblastoma Multiforme		Anti-Tumor Immunotherapy Targeted Against Cytomegalovirus in Patients With Newly-Diagnosed Glioblastoma Multiforme During Recovery From Therapeutic
	Condition:	Brain and Central Nervous System Tumors	
	Interventions:	Biological: tetanus toxoid; Biological: therapeutic autologous dendritic cells; Biological: therapeutic autologous lymphocytes 2008	

	<p><b>Primary Outcome:</b> •Feasibility and safety of vaccination with cytomegalovirus pp65-LAMP mRNA-loaded dendritic cells (DCs) with or without autologous lymphocyte transfer [26 months ]</p> <p><b>Secondary Outcome:</b> •Humoral and cellular immune responses [26 months ]. /•Time to progression /•Differential ability of indium In-111-labeled DCs to track to the inguinal lymph nodes under different skin preparative conditions. /•Differential ability of indium In-111-labeled DCs to track to lymph nodes on the tumor bearing and non-tumor bearing side of the cervical lymph nodes. /•Immunologic cell infiltrate in recurrent tumors. /•Evidence of antigen-escape outgrowth in recurrent or progressive tumors.</p> <p>RATIONALE: Vaccines may help the body build an effective immune response to kill cancer cells. Radiation therapy uses high-energy x-rays to kill cancer cells. Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving vaccine therapy together with radiation therapy and chemotherapy may kill more cancer cells.</p>	
Completed	<p><b>Tumor RNA Transfected Dendritic Cell Vaccines</b></p> <p>Condition: Prostate Cancer</p> <p>Intervention: Biological: Tumor RNA transfected dendritic cells 2005</p>	
	<p><b>Purpose:</b> The purpose of this study is to use dendritic cells transfected with amplified RNA from autologous tumor cells to develop a vaccine strategy for the treatment of prostate cancer in patients with disseminated disease.</p> <p><b>Detailed Description:</b> The specific aims are: 1) to evaluate, in a phase I clinical trial, the safety of vaccinating patients with dendritic cells transfected with RNA from autologous cancer cells; 2) to analyze the T cell responses induced by the treatment; and 3) to improve the efficacy of the treatment by developing methods to increase the induction of CD4+T cell responses.</p>	
Active, not recruiting	<p><b>Antiangiogenic Peptide Vaccine Therapy With Gemcitabine in Treating Patient With Pancreatic Cancer (Phase1/2)</b></p> <p>Condition: Pancreatic Cancer</p> <p>Interventions: Biological: VEGFR1-1084, VEGFR2-169; Drug: Gemcitabine 2008</p>	
	<p><b>Purpose :</b> The purpose of this study is to evaluate the safety, and tolerability of HLA-A*2402 restricted epitope peptide VEGFR1 and VEGFR2 emulsified with Montanide ISA 51 in combination with gemcitabine.</p> <p><b>Primary Outcome:</b> •toxicities as assessed by NCI-CACAE ver3) [ 3 months ]</p> <p><b>Secondary Outcome:</b> •Differences of peptide specific CTL response in vitro among sequence of gemcitabine and peptide vaccine administration [3months]. /•CD8 population [3months]. /•Change in level of regulatory T cells [3months]. /•Objective response rate [ 1year ] . /•feasibility [ 1year ]. /</p> <p>•Survival [ 1year ]</p> <p><b>Detailed Description:</b> Vascular endothelial growth factor receptor 1 and 2 (VEGFR1 and VEGFR2) 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 in vivo. According to these findings, in this trial, we evaluate the safety, tolerability and immune response of these peptide emulsified with Montanide ISA 51 in combination with gemcitabine</p>	
Completed	<p><b>Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Esophageal Cancer</b></p> <p>Condition: Esophageal Cancer 東大</p> <p>Intervention: Biological: URLC10, VEGFR1 and VEGFR2 2008</p>	
	<p>Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 for Refractory Esophageal Cancer</p>	

	<p><b>Primary Outcome:</b> •Safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [ Time Frame: two months ]</p> <p><b>Secondary Outcome:</b> •To evaluate immunological responses [ two months ]</p> <p><b>Detailed Description:</b> URLC10 has been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 is upregulated in human esophageal tumors. 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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, the URLC10-117 peptide(1mg), VEGFR1 peptide(1mg) and VEGFR2 peptide(1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>					
Completed	<p><u>Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Esophageal Cancer</u></p> <table border="1"> <tr> <td>Condition:</td> <td>Esophageal Cancer 東大</td> </tr> <tr> <td>Intervention:</td> <td>Biological: URC10, TTK, KOC1 2008</td> </tr> </table>		Condition:	Esophageal Cancer 東大	Intervention:	Biological: URC10, TTK, KOC1 2008
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Intervention:	Biological: URC10, TTK, KOC1 2008					
	<p>Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*2402 for Refractory Esophageal Cancer</p>					
	<p>Primary Outcome: Safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [2 months]</p> <p>Secondary Outcome: •To evaluate immunological responses [2 months ].</p> <p><b>Detailed Description:</b> URLC10, KOC1 and TTK have been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10, KOC1 and TTK are upregulated in human esophageal tumors. We identified that peptides derived from these proteins 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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, the URLC10 peptide (1mg), KOC1 peptide (1mg), and TTK peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>					
Completed	<p><u>Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Gastric Cancer</u></p> <table border="1"> <tr> <td>Condition:</td> <td>Gastric Cancer</td> </tr> <tr> <td>Intervention:</td> <td>Biological: URLC10, VEGFR1 and VEGFR2 2008</td> </tr> </table>		Condition:	Gastric Cancer	Intervention:	Biological: URLC10, VEGFR1 and VEGFR2 2008
Condition:	Gastric Cancer					
Intervention:	Biological: URLC10, VEGFR1 and VEGFR2 2008					
	<p>Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 for Refractory Gastric Cancer</p>					

	<p><b>Primary Outcome:</b> safety (Phase I: toxicities as assessed by NCI CTCAE version 3) and efficacy (Phase II: evaluated by RECIST) [2 mo]</p> <p><b>Secondary Outcome:</b> •To evaluate immunological responses [ two months ]</p> <p><b>Detailed Description:</b> URLC10 has been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 is upregulated in human gastric tumors. 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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, the URLC10-117 peptide (1mg), VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. The patients will also receive oral chemotherapy (S-1) simultaneously. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>	
Completed	<p><u>Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Gastric Cancer</u></p>	
	Condition:	Gastric Cancer
	Intervention:	Biological: URLC10, KOC1, VEGFR1 and VEGFR2 2008
	<p><b>Primary Outcome:</b> •safety (Phase I: toxicities as assessed by NCI CTCAE version 3) and efficacy (Phase II: Feasibility as evaluated by RECIST) 2 months ].</p> <p><b>Secondary Outcom:</b> •To evaluate immunological responses [ Time Frame: two months ]</p> <p><b>Detailed Description:</b> URLC10 and KOC1 have been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 and KOC1 are upregulated in human gastric tumors. 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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, the URLC10 peptide (1mg), KOC1 peptide (1mg), VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. The patients will also receive oral chemotherapy (S-1) simultaneously. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>	
Recruiting	<p><u>Reduced Intensity Stem Cell Transplantation for Chronic Lymphocytic Leukemia Followed by Vaccination</u></p>	
	Condition:	Chronic Lymphocytic Leukemia
	Interventions:	Biological: GM-K562 vaccine; Procedure: stem cell transplantation 2007
	<p>Stem Cell Transplantation for Advanced CLL Followed by Vaccination With Lethally Irradiated Autologous Tumor Cells Admixed With GM-CSF Secreting K562 Cells</p>	

	<p><b>Primary Outcome:</b>•To assess the safety and toxicity of vaccination with lethally irradiated autologous CLL cells admixed with GM-562 cells following reduced intensity allogeneic stem cell transplant for CLL patients with advanced disease. [: 2 years ]</p> <p><b>Secondary Outcome:</b> •To characterize the biologic activity in response to vaccination with lethally irradiated autologous CLL cells admixed with GM-562 cells, following reduced intensity allogeneic stem cell transplant [2 years ]. #to estimate duration of disease response, disease free and overall survival. [2 years ]</p> <p>Detailed Description:</p> <ul style="list-style-type: none"> <li>•This study can be divided into four phases: 1) Screening; 2) Reduced intensity transplant phase; 3) Vaccinations (cycle 1 and cycle 2:each cycle lasts 7 weeks) and 4) Vaccine completion.</li> <li>•Screening Phase: After signing the consent form, participants will be asked to undergo some screening tests and procedures to find out if they are eligible to participate in the study. These tests and procedures are likely to be part of regular cancer care and may be done even if the patient does not take part in the research study. It is important to note that if insufficient numbers of the participants leukemia cells to generate vaccine were collected on the CLL collection and banking study (DFHCC study #06-200), then they will not be eligible to participate in this study.</li> <li>•Allogeneic reduced intensity stem cell transplant phase: The transplant phase of the study will begin when the participant is admitted to the hospital to receive chemotherapy and stem cell transplant. The minimum duration of hospitalization for the procedure is approximately 8 days. Undergoing transplant involves the following procedures and treatments: Central intravenous catheter; chemotherapy; medications to prevent graft versus host disease (GVHD); medication to prevent infections; physical exams; blood tests and bone marrow biopsy and aspirate.</li> <li>•Vaccination Phase: Vaccinations will be given in two cycles, of seven weeks each, that are identical with the exception of when they are administered. Cycle 1 vaccination will begin approximately one month after the stem cells have been infused, provided there is no significant evidence of GVHD. Cycle 2 vaccination will be being approximately one month after discontinuing tacrolimus, provided there is no evidence of severe acute or chronic GVHD. The vaccine will be given 6 times over a period of two months. The participant will receive vaccination shots once weekly for 3 vaccines and then every other week for 3 vaccines.</li> <li>•Skin biopsies will be done after the first and after the fifth vaccinations. Current status of the participants CLL will be assessed to determine how the disease has responded to transplant and vaccination. These tests include analysis of bone marrow and blood tests.</li> <li>•Vaccine completion phase: After one cycle of vaccination is completed, the participant will return to the outpatient clinic monthly for check-ups for 6 visits, to monitor the effects of the vaccine.</li> <li>•Since this trial involves the use of genetically modified cells, it is recommended that participants on this trial undergo annual checkups for at least 20 years, in order to monitor for long term effects of the vaccination treatment.</li> </ul>	
Recruiting	<u>Autologous OC-DC Vaccine in Ovarian Cancer</u>	Dendritic Cell Vaccine Loaded With
	Conditions: Chemotherapy; Tumor; Ovarian Cancer	Autologous Tumor for Recurrent Ovarian,
	Intervention: Biological: ODCD 2010	Primary Peritoneal or Fallopian Tube Cancer

	<p><b>Primary Outcome:</b> •Safety [30 days]. /Safety will be established by grading the observed toxicities using the NCI Common Toxicity Criteria (CTC Version3.0). All toxicities observed within 30 days of last vaccination will be included.</p> <p><b>Secondary Outcome:</b> •Clinical Response. /Clinical Response will be determined by RECIST criteria. Response rate is the proportion of patients that achieve CR or PR. /•Dose limiting toxicity. /Dose-limiting toxicity is defined as: any Grade 3 or higher allergic, autoimmune or injection site reaction or any Grade 4 hematologic or non-hematologic toxicity (except fever). /•Immune Response Immune Response. /Immune response will be evaluated by IFN-g ELISPOT analysis of tumor-reactive T cells, and in HLA2+ subjects, by tetramer analysis of Her-2 specific T cells in peripheral blood. Response is defined by a 3 fold increase relative to pre-vaccination.</p> <p><b>Detailed Description:</b> The primary objective is to compare the feasibility and safety of administering OC-DC intranodally alone or and in combination with either intravenous Daclizumab alone or intravenous Bevacizumab and Daclizumab in subjects with recurrent ovarian, fallopian tube, primary peritoneal or papillary serous endometrial cancer. The secondary objective is to assess the immunogenicity of OC-DC administered alone or combined with either intravenous Daclizumab alone or intravenous Bevacizumab and Daclizumab and to assess the effect of OC-DC alone or combined with either intravenous Daclizumab alone or intravenous Bevacizumab and Daclizumab on peripheral blood T cell subsets including regulatory T cells and finally to asses the clinical response rates.</p>	
Completed	<p><u>Vaccination of Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype</u></p> <p>Conditions: B Cell Lymphoma; Follicular Lymphoma; Neoplasm</p> <p>Interventions: Drug: Id-KLH Vaccine; Drug: QS-21 (Stimulation-QS-21) Drug 1999</p>	Vaccination of Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype
	<p><b>Detailed Description:</b> The idiotype of the immunoglobulin on a given B cell malignancy (Id) can serve as a clonal marker, and a previous pilot study in lymphoma patients has demonstrated that autologous Id protein can be formulated into an immunogenic, tumor specific antigen by conjugation to a carrier protein (KLH) and administration with an emulsion-based adjuvant.</p> <p>The objectives of this study are: 1) to evaluate feasibility and toxicity of new vaccine formulations, and 2) to evaluate cellular and humoral immune responses against the unique idiotype of the patient's lymphoma.</p> <p>The goal of this study is to treat patients with follicular lymphomas to complete remission or minimal residual disease with chemotherapy. Six to twelve months after completion of chemotherapy, in an effort to reduce the relapse rate (by eradicating microscopic disease resistant to chemotherapy), patients will receive one of two new formulations of an autologous Id vaccine.</p>	
Terminated	<p><u>Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Breast Cancer</u></p> <p>Condition: Breast Cancer</p> <p>Intervention: Biological: TTK peptide mixed with Montanide ISA 51 2008</p>	Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*2402 for Refractory Breast Cancer
	<p><b>Primary Outcome:</b> •safety (Phase I: toxicities as assessed by NCI CTCAE version3) and efficacy (Phase II: feasibility as evaluated by RECIST) [2 months ]</p> <p><b>Secondary Outcome:</b> •to evaluate immunological responses [ Time Frame: 2 months ]</p> <p><b>Detailed Description:</b> TTK has been identified as cancer specific molecules especially in breast cancer using genome-wide expression profile analysis by cDNA microarray technique. We have determined the HLA-A*2402 restricted epitope peptide derived from this molecule and identified that this peptide significantly induces 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 that peptide. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, TTK-A24-567 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of this peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>	
Active, not recruiting	<p><u>Vaccine Therapy and Sargramostim in Treating Patients With Soft Tissue Sarcoma</u></p> <p>Condition: Sarcoma</p> <p>Interventions: Biological: NY-ESO-1 peptide vaccine; Biological: sargramostim 2001</p>	NY-ESO-1 Immunization in Patients With NY-ESO-1/LAGE Antigen Expressing Cancer



	<p><b>OBJECTIVES:</b> •Determine the safety and tolerability of NY-ESO-1 peptide vaccine and sargramostim (GM-CSF) in patients with stage II, III, or IV soft tissue sarcoma expressing NY-ESO-1 or LAGE antigen. /•Determine the immunologic profile (NY-ESO-1 antibody, CD8+ cells, and delayed-type hypersensitivity) in patients treated with this regimen. /•Determine tumor responses in patients treated with this regimen.15 patients will be accrued for this study within 12 months</p>	
Recruiting	<p><u>Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Non-Small Cell Lung</u></p> <p>Condition: Non Small Cell Lung Cancer</p> <p>Intervention: Biological: URLC10, TTK and KOC1 2008</p>	<p>Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201for Refractory Non-Small Cell Lung Cancer</p>
	<p><b>Primary Outcome:</b> •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [ two months ]</p> <p><b>Secondary Outcome:</b> •To evaluate immunological responses [ Time Frame: two months ]</p> <p>Detailed Description: URLC10,TTK and KOC1 has 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 and identified that these peptides 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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, the URLC10-177 peptide(1mg), TTK-567 peptide(1mg) and KOC1-508 peptide(1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>	
Recruiting	<p><u>Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Non-Small Cell Lung</u></p> <p>Condition: Non Small Cell Lung Cancer</p> <p>Intervention: Biological: URLC10, VEGFR1 and VEGFR2 2008</p>	<p>Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 for Refractory Non-Small Cell Lung Cancer</p>
	<p><b>Primary Outcome:</b>•safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [ two months ]</p> <p><b>Secondary Outcome:</b> •To evaluate immunological responses [two months ] •Time to progression [ one years ]</p> <p><b>Detailed Description:</b> URLC10 has 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*0201 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. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, the URLC10-117 peptide(1mg), VEGFR1 peptide(1mg) and VEGFR2 peptide(1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>	
Suspended	<p><u>Vaccine Therapy in Treating Patients With Stage III or Stage IV Melanoma</u></p> <p>Condition: Melanoma (Skin) 2006</p> <p>Interventions: Biological: PADRE 965.10; Biological: alpha-type-1 polarized dendritic cells; Biological: keyhole limpet hemocyanin; Biological: therapeutic autologous dendritic cells; Other: immunoenzyme technique</p>	<p>Alpha-Type-1 DC-Based and cDC-Based Intralymphatic Vaccines in Patients With Metastatic Melanoma</p>

	<p><b>Primary Outcome:</b> •Safety of intralymphatic autologous type-1-polarized dendritic cell vaccine and autologous mature dendritic cell vaccine. /•Cumulative increase in the sum of specific interferon gamma ELISPOTs against melanoma-specific A2-restricted peptides.  <b>Secondary Outcome:</b> •Peripheral blood CD8+ and CD4+ T-cell response to HLA-presented melanoma epitopes and autologous tumor cells by interferon gamma and interleukin-5 ELISPOT assay. /•Delayed-type hypersensitivity (DTH) response to treatment /DTH response to keyhole limpet hemocyanin and pan-DR epitope (PADRE)./ •Correlation of treatment-associated changes in immune response with clinical outcome.          patients are followed periodically for 10½ years and then annually thereafter</p>	
Recruiting	<p><u>Unimolecular Pentavalent (Globo-H-GM2-sTn-TF-Tn) Immunization of Patients With Epithelial Ovarian, Fallopian Tube, or</u>          Conditions: Fallopian Tubes; Ovarian Cancer; Peritoneal Cancer          Intervention: Biological: Globo-H-GM2-sTn-TF-Tn-KLH conjugate, plus the immunological adjuvant QS-21 2010</p>	<p>Unimolecular Pentavalent (Globo-H-GM2-sTn-TF-Tn) Immunization for Epithelial Ovarian, Fallopian Tube, or Peritoneal</p>
	<p><b>Primary Outcome:</b> •To determine immunologic response [6 months ]. /immunization with the unimolecular pentavalent carbohydrate-based vaccine bearing Globo-H, GM2, sTn, TF and Tn on a single polypeptide backbone, conjugated to KLH, mixed with the immunological adjuvant QS-21, induces an IgG and IgM antibody response against these individual antigens and tumor cells expressing these antigens. /•To determine the toxicities following immunization with this unimolecular polyvalent vaccine. [2 years ] /Toxicity will be graded in accordance with the Common Toxicity Criteria Version 4.0 developed by the National Cancer Institute (NCI). /•To determine the maximum tolerated dose over three dose levels. [2 years ]. /Six patients will be accrued to one of three pentavalent vaccine doses (25 mcg, 50 mcg and 100 mcg), and an expansion cohort of six patients will be enrolled at the highest dose level achieved. <b>Secondary Outcome:</b> •To record the progression free interval [ 2 years ]</p>	
Not yet recruiting	<p><u>Survivin Vaccine Therapy for Patients With Malignant Gliomas</u>          Conditions: Adult Anaplastic Astrocytoma; Adult Anaplastic Oligodendroglioma; Adult Giant Cell Glioblastoma; Adult Glioblastoma; Adult Gliosarcoma; Adult Mixed Glioma; Recurrent Adult Brain Tumor          Interventions: Drug: Montanide ISA-51/survivin peptide vaccine; Biological: sargramostim; Other: flow cytometry; Other: laboratory biomarker analysis; Other: immunoenzyme technique 2010</p>	<p>Immunological Effects of SVN53-67/M57-KLH (012410-2) in Patients With Survivin-Positive Malignant Gliomas</p>
	<p><b>Primary Outcome:</b> •Toxicity of drug (012140-2) [ after first dose for 24 weeks, death or progression ]  <b>Secondary Outcome:</b> •Immune response [weeks 2, 4, 6,12, 16, 20 and 24 ]. •Therapeutic efficacy [weeks 8 and 12 ]  <b>Detailed Description:</b> PRIMARY OBJECTIVES: I. To determine the toxicity profile of the SVN53-67/M57-KLH peptide in Montanide ISA 51 plus with GM-CSF. SECONDARY OBJECTIVES: I. To measure the immune responses induced by SVN53-67/M57-KLH with Montanide ISA 51 with GM-CSF. TERTIARY OBJECTIVES: I. To collect preliminary data on therapeutic efficacy of this combination against malignant glioma. OUTLINE: Patients receive montanide ISA-51/survivin peptide vaccine subcutaneously (SC) followed by sargramostim SC on day 0. Treatment repeats every 2 weeks for 4 courses in the absence of disease progression or unacceptable toxicity. After completion of study treatment patients are followed up at weeks 16, 20, and 24.</p>	
Active, not recruiting	<p><u>Vaccine Trial for Clear Cell Sarcoma, Pediatric Renal Cell Carcinoma, Alveolar Soft Part Sarcoma and Children With Stage IV</u>          Conditions: Sarcoma, Clear Cell; Sarcoma, Alveolar Soft Part; Renal Cell Carcinoma; Melanoma          Intervention: Biological: GVAX 2005</p>	<p>Vaccination With Autologous, Lethally Irradiated Tumor Cells Engineered by Adenoviral Mediated Gene Transfer to Secrete GM-CSF</p>

	<p><b>Primary Outcome:</b> •To determine the safety and feasibility of preparation and administration of vaccine in patients with metastatic or locally advanced clear cell sarcoma (CCS), alveolar soft part sarcoma (ASPS) and translocation associated renal cell carcinoma (RCC) [ Years ]</p> <p><b>Secondary Outcome:</b> •To determine the disease response, immune response, and overall survival rate.</p> <p>Reaction of the immune system caused by the vaccine; This injection is measuring delayed type hypersensitivity, or DTH. The patient will be asked to undergo optional skin biopsies of the vaccine and DTH sites to see if an immune reaction is occurring at the injection sites 2 days after vaccine 1 and vaccine 5.</p> <p>At week 10 in the patient's treatment, or earlier if the doctor feels it is necessary, the patient will undergo a chest, abdomen and pelvic XT scan. A brain MRI will be performed if there were any abnormalities on the first brain MRI or if any new central nervous system symptoms have developed.</p>	
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Stage IIB, Stage IIC, Stage III, or Stage IV Melanoma</u>	
	Conditions:	Intraocular Melanoma; Melanoma (Skin) 2006
	Interventions:	Biological: mouse gp100 plasmid DNA vaccine; Procedure: adjuvant therapy
	<p><b>Primary Outcome:</b> •Safety of particle-mediated epidermal delivery (PMED) of mouse gp100 plasmid DNA vaccine. /•Comparison of PMED-based DNA immunization with intramuscular jet immunization, based on T-cell response. <b>Secondary Outcome:</b> •Antitumor response.</p> <p>patients are followed periodically for 1 year.</p>	
Recruiting	<u>Randomized Study of Adjuvant WT-1 Analog Peptide Vaccine in Patients With Malignant Pleural Mesothelioma (MPM) After</u>	
	Condition:	Malignant Pleural Mesothelioma 2010
	Interventions:	Biological: WT-1-vaccine Montanide + GM-CSF; Biological: Montanide adjuvant + GM-CSF
	<p><b>Primary Outcome:</b> •To assess the 1-year progression free survival in patients [ Time Frame: 1 year ] treated with WT-1 analog peptide vaccine + GM-CSF or Montanide + GM-CSF after completion of combined modality therapy for Malignant Pleural Mesothelioma (MPM).</p> <p><b>Secondary Outcome:</b> •To confirm the immunogenicity of the WT-1 analog peptide vaccine [1 year ]for MPM after completion of combined modality therapy. /•To assess the utility of using serum markers [1 year ]. /(soluble mesothelin related protein (SMRP) and osteopontin)for MPM for disease progression.</p> <p>The addition of the WT1 proteins makes this therapy more directed to mesothelioma. The combination of WT1 vaccine with Montanide and GM-CSF has been tested in a prior trial including 9 patients with advanced mesothelioma. In that trial, the vaccine was safe and caused an immune response. The patient will have a 50% chance of being in each group. Neither the patient nor the doctor will be aware of which group they are in.</p>	
Recruiting	<u>Influenza Vaccine Post Allogeneic Transplant</u>	
	Conditions:	Hematopoietic Stem Cell Transplant; Hematologic Malignancy
	Intervention:	Biological: Influenza vaccine
Active, not recruiting	<u>Multiple-Vaccine Therapy in Treating Patients With Non-Small Cell Lung Cancer</u>	
	Condition:	Non Small Cell Lung Cancer 福島医科大学
	Intervention:	Biological: HLA-A*2402restricted URLC10, TTK, VEGFR1 and VEGFR2 2008

Injection of AJCC Stage IIB, IIC, III and IV Melanoma Patients With Mouse gp100 DNA:

Adjuvant WT-1 Analog Peptide Vaccine in Patients With Malignant Pleural Mesothelioma (MPM)

MT2010-08R Influenza Vaccine Specific Immune Responses After Allogeneic Hematopoietic Cell Transplantation: Are One or Two Vaccine Doses Needed?

Multiple-Vaccine Therapy Including Antiangiogenic Vaccine Using Epitope Peptide Restricted to HLA-A\*2402 for

	<p><b>Primary Outcome:</b> •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 [3 months ]</p> <p><b>Secondary Outcome:</b> •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 ]</p> <p><b>Detailed Description:</b> URLC10 and TTK 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,</p>	
Recruiting	<p><u>Bivalent Vaccine With Escalating Doses of the Immunological Adjuvant OPT-821, in Combination With Oral <math>\beta</math>-glucan for High-</u></p> <p>Condition: Neuroblastoma 2009</p> <p>Intervention: Biological: adjuvant OPT-821 in a vaccine containing two antigens (GD2L and GD3L) covalently linked to KLH</p>	<p>Bivalent Vaccine With Escalating Doses of the Immunological Adjuvant OPT-821, in Combination With Oral <math>\beta</math>-glucan for High-Risk Neuroblastoma</p>
	<p><b>Primary Outcome:</b> Determine the maximally tolerated dose of OPT-821 in a vaccine containing two antigens abundantly expressed on neuroblastoma. [ 2 years ]</p> <p><b>Secondary Outcome:</b> •To obtain preliminary data on whether subcutaneous administration of the bivalent vaccine produces an immune response directed against the target antigens in patients with high-risk neuroblastoma. [2 years ] /•To obtain preliminary data on the anti-neuroblastoma activity of the bivalent vaccine plus oral <math>\beta</math>-glucan in patients, including measuring the molecular response in blood and bone marrow. [ Time Frame: 2 years ]</p> <p>We want the vaccine to cause the patient's immune system to make antibodies against the antigens. Antibodies are made by the body to attack cancer (and to fight infections). If the patient can make antibodies against the 2 antigens in the vaccine, those antibodies might also attach to neuroblastoma cells because a lot of each antigen is on neuroblastoma (and very little on other parts of the body). Then, the attached antibodies would attract the patient's white blood cells to kill the neuroblastoma. This protocol also uses <math>\beta</math>-glucan which is a kind of sugar from yeast. <math>\beta</math>-glucan is taken by mouth and can help white blood cells kill cancer. The best way to get the body to make antibodies against the 3 antigens is to link each antigen to a protein called KLH (which stands for: keyhole limpet hemocyanin) and to mix them with a substance called QS-21. But it is hard to get enough QS-21 so we are using an identical substance called OPT-821, which we can get easily in large amounts for use in patients. Studies in adults show that giving these antigens linked to KLH and mixed with QS-21 is safe but there can be some bad side effects on the liver and they can last as long as a few months. Instead of the QS-21, we want to know how much of the OPT-821 can be used safely in children. We want to find the highest dose of OPT-821 that is safe to use with the vaccine. We think that higher doses of OPT-821 are better for killing the cancer but we do not know if that is true.</p>	
Recruiting	<p><u>Alternate Dosing Schedules Study for HPV Vaccine</u></p> <p>Conditions: Cervical Cancer; Genital Warts</p> <p>Intervention:</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Stage III or Stage IV Melanoma</u></p> <p>Condition: Melanoma (Skin) 2004</p> <p>Interventions: Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells</p>	<p>En Vivo Matured Dendritic Cell Therapy in Patients With Melanoma</p>