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

The purpose of this study is to test the safety of an investigational vaccine called TroVax when given in conjunction with Interleukin-2 (IL-2) treatment. TroVax is the experimental product in this trial and its value as a medicine has not yet been proven. Interleukin-2 (IL-2) is standard treatment for your cancer, which means that you could receive it even if you choose not to participate in this study. TroVax is being studied as a possible treatment for patients with cancer of the kidney.
TroVax belongs to a class of medicines called a vaccine. A vaccine helps the body's immune system to recognize and kill foreign invading organisms effectively. It is believed that one of the reasons why cancer can spread through the body is that the immune system cannot recognize them as being different from normal tissues and therefore cannot kill the cancer cells. A vaccine that alerts the immune system to the presence of cancer cells in the body could lead to the immune system being able to target and kill those cancer cells effectively. This trial is of a completely new way of trying to treat cancer in the future by the use of vaccination injections. **TroVax consists of a virus that has been changed so that it is no longer infectious and carries a gene for a protein called 5T4.** This protein is carried by many kidney cancer calls. When the virus is injected, it makes the protein, and the body's immune system is then able to recognize this protein and kill the cells that have it (i.e. the cancer cells).
The purpose of this study is to assess the safety and tolerability of TroVax injections and to understand whether TroVax could make such an immune response happen in patients with renal cell cancer while receiving Interleukin-2 (IL-2). This study will also observe and monitor any side effects experienced in patients who receive TroVax while being treated with IL-2.
Primary Outcome Measures: safety [Time Frame: duration of study] Estimated Enrollment: 25 Study Start Date: August 2004 - : July 2008
Primary Completion Date: July 2008 (Final data collection date for primary outcome measure)
Intervention Details: Biological: TroVax in combination with IL-2 1ml intramuscular injection

Recruiting

Vaccine Therapy in Treating Patients With Metastatic Melanoma

Condition:	Melanoma (Skin)
Interventions:	Biological: **autologous dendritic cell-adenovirus CCL21** vaccine; Other: flow cytometry; Other: fluorescence activated cell sorting; Other: immunoenzyme technique; Other: immunohistochemistry staining method; Other: laboratory biomarker analysis

A Dose Ranging Trial of Adenovirus CCL-21 Transduced MART-1/gp100 Peptide-Pulsed Dendritic Cells Matured Using Cytokines for Patients With Chemotherapy-Resistant Metastatic Melanoma.
OBJECTIVES: To assess the toxicity and immune responses in patients with HLA-A*0201-positive, chemotherapy-resistant, metastatic melanoma treated with escalating doses of autologous dendritic cell-adenovirus CCL21 vaccine.
To assess clinical responses in these patients.
OUTLINE: Patients receive intradermal injections of autologous dendritic cell-adenovirus CCL21 vaccine once on days 1, 8, 22, and 36. Patients achieving stable disease or response to therapy may receive a second course at least 1 and no more than 6 months from the last vaccine administration.
Blood samples are collected at baseline and after treatment for immunologic studies. Samples are analyzed for MART-1 and gp100-specific CD8+ T-cells and KLH-specific CD4+ T helper cells by ELISPOT assay; cytotoxic T-cells by chromium release assays; and CD8+ T-cells by tetramer-specific flow cytometry and FACS analysis. Patients also undergo tissue biopsies after treatment. Tissue samples are analyzed for numbers of CD3, CD8, CD4 T-cells, CD56 NK, and CD19 B-cells, and levels of local CCL21 by IHC.
After completion of study treatment, patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter.

Completed

Vaccine Therapy in Treating Patients With Advanced Cancer

Condition:	Unspecified Adult Solid Tumor, Protocol Specific
Intervention:	Biological: TG4010

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

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

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

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

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

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

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

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