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| | <p>Primary : Is to assess the safety and tolerability of MKC1106-MT regimen [Time Frame: 6 weeks]</p> <p>Secondary: To assess the immune response (by tetramer and ELISPOT analysis) of MKC1106-MT when administered to subjects with advanced melanoma [6 Weeks. /To determine pMEL-TYR plasmid level in the blood by PCR analysis [6 Weeks] /To determine target antigen expression (Melan A and tyrosinase) and beta2 microglobulin expression in the tumor tissue [6 Weeks]. /To document any preliminary evidence of clinical response [Time Frame: 6 Weeks]</p> <p>Detailed Description: The multi-component active immunotherapy, MKC1106-MT, consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune reaction to two tumor associated antigens (Melan-A and tyrosinase). The plasmid component will be administered on Days 1,4, 15 and 18 of each treatment cycle followed by administration of peptides on Days 29 and 32 of the treatment cycle. All components will be administered separately into superficial inguinal lymph nodes under ultrasound guidance.</p> | |
| Recruiting | <p>Safety Study of a Liposomal Vaccine to Treat Malignant Melanoma</p> <p>Condition: Melanoma</p> <p>Intervention: Biological: Lipovaxin-MM 2010</p> | Lipovaxin-MM: |
| | <p>Primary: Adverse events [Time Frame: Within 112 days after first dose]. /Immunogenicity [Within 112 days of first dose]</p> <p>Secondary : Anti-cancer activity (RECIST criteria) [Time Frame: Within 112 days of first dose]</p> <p>The purpose of this study is to determine whether Lipovaxin-MM, a new anti-cancer vaccine, is safe and effective in improving the body's ability to destroy cancer cells in patients with metastatic melanoma.</p> | |
| Completed | <p>RNA-Loaded Dendritic Cell Cancer Vaccine</p> <p>Condition: Renal Cell Carcinoma</p> <p>Intervention: Biological: Dendritic cell vaccine 2004</p> | Dendritic cell vaccine |
| | The purpose of this trial is to examine the safety, feasibility, immunological response, and clinical antitumor activity of administering a dendritic cell vaccine to patients with metastatic renal cell carcinoma | |
| Recruiting | <p>Ovarian Cancer Vaccine for Patients in Remission</p> <p>Condition: Epithelial Ovarian Cancer</p> <p>Intervention: Biological: MUC1 Dendritic Cell Vaccine (CVac) 2010</p> | MUC1 Dendritic Cell Vaccine (CVac) a MUC1 Dendritic Cell Vaccine PFS. |
| | <p>Primary: To evaluate the safety of CVac administration in this population. [: 2 years] /Progression Free Survival [2 years]</p> <p>Secondary: Overall survival [2 years]. / Evaluation of immunologic parameters subsequent to CVac administration. [2 years]</p> | |
| Recruiting | <p>Four Doses of MAGE Vaccine for Patients With Squamous Cell Carcinoma of the Head and Neck</p> <p>Conditions: Squamous Cell Carcinoma; Head and Neck Cancer</p> <p>Intervention: Biological: MAGE-A3 HPV-16 vaccine 2008</p> | MAGE-A3 HPV-16 vaccine. Four Doses of MAGE-A3/HPV 16 Trojan Peptides |
| | <p>Purpose: Squamous Cell Carcinoma of the Head and Neck (SCCHN) effects 43,000 individuals in the United States annually with an estimated overall survival of 50%. For some patients who develop local or distant metastases following primary therapy, surgery is not an option. This study is being done to test the safety of experimental cancer vaccines made of MAGE-A3 and HPV-16 antigens. We also hope to learn what doses of the vaccine will best stimulate the immune system. There will be 2 cohorts in this study, based on the results of tumor testing: Cohort 1: Patients with tumor that is HPV 16 positive Cohort 2: Patients with tumor that is MAGE-A3 positive</p> <p>Primary: to test the safety of the experimental cancer vaccines made of MAGE-A3 and HPV-16 antigens [Time Frame: ongoing</p> <p>Secondary: to learn what doses of the vaccine will best stimulate the immune system</p> | |

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| Not yet recruiting | Safety, Immune and Tumor Response to a Multi-component Immune Based Therapy (MKC1106-MT) for Patients With Melanoma | | MKC1106-MT: consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune reaction to two tumor associated antigens (Melan-A and tyrosinase). |
| | Condition: | Stage III Melanoma, Stage IV Melanoma | |
| | Intervention: | Biological: MKC1106-MT 2009 | |
| | <p>Primary: To evaluate the objective response, where response is defined as either complete response (CR), partial response (PR), or stable disease (SD) for 12 weeks or longer (CR, PR, and SD are defined according to RECIST 1.1 criteria) [Time Frame: 12 Months]</p> <p>Secondary: To assess clinical efficacy of MKC1106-MT in subjects with advanced melanoma measured at 6 months and 1 year by (1) time to progression, progression-free survival [Time Frame: 12 Months]. /To identify and characterize correlations between biological activity (immune response), target antigen expression and clinical efficacy. [Time Frame: 12 months]. /To further assess the safety profile and tolerability [Time Frame: 12 months]</p> <p>Detailed Description: The multi-component active immunotherapy, MKC1106-MT, consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune reaction to two tumor associated antigens (Melan-A and tyrosinase). The plasmid component will be administered on Days 1, 4, 15 and 18 of each treatment cycle followed by administration of peptides on Days 29 and 32 of the treatment cycle. All components will be administered separately into non-diseased superficial inguinal lymph nodes under ultrasound guidance</p> | | |
| Not yet recruiting | Allogeneic Whole Cell Cancer Vaccine for Metastatic Epithelial Tumors | | Allogeneic whole epithelial tumor cells, DNP-conjugated and irradiated |
| | Conditions: | Colorectal Cancer; Ovarian Cancer; Gastric Cancer; Breast Cancer; Lung Cancer | |
| | Intervention: | Biological: Allogeneic whole epithelial tumor cells, DNP-conjugated and irradiated 2008 | |
| | <p>Purpose This study is based on the finding that tumor cells that are grown in the laboratory can be modified in such a way that, when injected to the patient, they will stimulate his/her immune response. This approach will be evaluated in patients with colorectal, gastric, ovarian, breast or lung epithelial cancer. Tumor cells grown in the laboratory will be modified to make them stimulatory to the immune system, irradiated to kill them, and injected to the patient eight times at two-week intervals . This protocol is expected to prolong survival of metastatic epithelial cancer patients.</p> | | |
| Recruiting | A Phase I Cancer Vaccine Study for Patients With Metastatic Breast Cancer | | Dendritic Cell Vaccination: Autologous Dendritic Cells Loaded With Oncofetal Antigen/iLRP. |
| | Condition: | Metastatic Breast Cancer | |
| | Intervention: | Biological: Dendritic Cell Vaccination 2008 | |
| | <p>Primary: toxicity [Time Frame: 24 months] [Designated as safety issue: Yes]</p> <p>Secondary : Response, Survival, Immunological Monitoring, Time to Disease Progression [Time Frame: 24 months]</p> <p>Detailed: The study is an open-label study to assess safety and immune responses to the universal tumor antigen OFA/iLRP. All patients will be immunized with 1 x 10⁷ viable OFA/iLRP-loaded mature, autologous monocyte-derived dendritic cells (DCs). The DC vaccine will be administered intradermally into the proximal medial upper extremity, contralateral to the original site of breast cancer once every month for 3 months. Changes in the tumor will be documented. The patient will remain in the study unless toxicity or adverse side effects require discontinuation following RECIST and CTC guidelines, or if the patient withdraws for any other reason.</p> | | |
| Terminated | Clinical Trial Studying a Personalized Cancer Vaccine in Patients With Non-Metastatic Kidney Cancer | | HSPPC-96: Adjuvant Oncophage® Versus Observation. |
| | Conditions: | Kidney Cancer; Renal Cell Carcinoma 2005 | |
| | Intervention: | Biological: HSPPC-96: protein peptide complex consisting of a 96 kDa heat shock protein (Hsp), gp96 | |

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| | <p>Primary: To determine whether patients randomized to receive adjuvant HSPPC-96 (treatment) after surgical resection of the kidney cancer have improved recurrence-free survival as compared to patients who did not receive adjuvant treatment (observation)</p> <p>Secondary: To determine whether patients randomized to receive adjuvant HSPPC-96 have improved overall survival as compared to patients in the observation group (without adjuvant treatment). /To further characterize the safety profile of HSPPC-96</p> <p>Detailed: This is an international, open label, randomized Phase 3 trial in which patients with surgically removable kidney cancer will be randomly selected post-operatively to receive adjuvant treatment with HSPPC-96 or no adjuvant treatment. All patients will undergo complete surgical removal of their tumors. The primary objective of the study is to determine whether patients who receive adjuvant autologous HSPPC-96 (treatment group) after surgical resection of locally advanced renal cell carcinoma have improved recurrence-free survival as compared to patients who are not receiving adjuvant treatment (observation group). Eligible patients will have a 50% chance of receiving adjuvant treatment with HSPPC-96. Patients in the treatment arm of the trial will receive the vaccine once a week for 4 weeks, and then every other week until vaccine depletion or disease recurrence. Both groups of patients will be followed regularly for assessment of their disease status.</p> <p>HSPPC-96 is an investigational, immunotherapeutic agent made from an individual patients own tumor, which is collected at the time of surgery. A portion of the tumor tissue is sent to Antigenics' manufacturing facility where it will undergo processing to create a vaccine.</p> | |
| Completed | NY-ESO-1 Protein With Montanide and CpG 7909 as Cancer Vaccine in Several Tumors | NY-ESO-1 protein with CpG 7909 and Montanide. Vaccination With NY-ESO-1 Recombinant Protein Mixed With CpG7909 and Montanide |
| | Condition: Tumors | |
| | Intervention: Biological: NY-ESO-1 protein with CpG 7909 and Montanide 2006 | |
| | <p>Purpose] This is a phase I, open-label, randomized study of NY-ESO-I protein with immune adjuvants CpG 7909 and Montanide® ISA-51 and NY-ESO-I protein 400 µg with immune adjuvants CpG 7909 and Montanide® ISA-51 in patients with tumors that often express NY-ESO-1. The vaccinations will be administered subcutaneously every 3 weeks for 4 doses. Patients with any malignancy that is known to frequently express NY-ESO-1 will be eligible, regardless of whether antigen expression in the autologous tumor can be demonstrated or not by either PCR or immunohistochemistry.</p> <p>Primary objective: safety. Secondarily, the study will evaluate whether patients develop a specific immunologic response to the NY-ESO-1 protein. Blood samples will be obtained at baseline, prior to each vaccination, one week after each vaccination, and at the last study visit for the assessment of NY-ESO-1 specific CD4+ and CD8+ T-cells. Cytokine secretion by NY-ESO-1 specific CD8+ and CD4+ T-cells, as a measure of T-cell activation, will be determined by FACS analysis. In addition, humoral immunity will be determined by the presence of NY-ESO-1 specific antibodies which will be assessed in all patients by ELISA. Disease status will be assessed at baseline and 2-4 weeks after the fourth vaccination in patients with evaluable (measurable and non-measurable disease).</p> | |
| Recruiting | Study to Assess dHER2+AS15 Cancer Vaccine Given in Combination With Lapatinib to Patients With Metastatic Breast Cancer | dHER2 + AS15 ASCI: dHER2 antigen combined with the immunostimulant. AS15 ASCI:: liquid adjuvant diluent. humoral and cellular immune response |
| | Condition: Metastatic Breast Cancer | |
| | Interventions: Biological: dHER2 + AS15 ASCI; Drug: Lapatinib | |
| Recruiting | A Phase I Safety Study of a Cancer Vaccine to Treat HLA-A2 Positive Advanced Stage Ovarian, Breast and Prostate Cancer | DPX-0907 consists of 7 tumor-specific HLA-A2-restricted peptides, a universal T Helper peptide, a polynucleotide adjuvant, a liposome and Montanide ISA51 VG. Cell mediated immunity |
| | Conditions: Ovarian Neoplasms; Breast Neoplasms; Prostatic Neoplasms | |
| | Intervention: Biological: DPX-0907 consists of 7 tumor-specific HLA-A2-restricted peptides, a universal T Helper peptide, a polynucleotide adjuvant, a liposome and Montanide ISA51 VG 2009 | |

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| | <p>Primary Outcome: The safety of dHER2+AS15 ASCI when administered in combination with Lapatinib measured by dose limiting toxicity. [Time Frame: 26 weeks]</p> <p>Secondary Outcome: The specific humoral and cellular immune response induced by the dHER2+AS15 ASCI upon co-administration of Lapatinib [26 weeks]</p> <p>This is a phase I/II study to determine the safety and gain insight into the immune response of the immunologic agent dHER2+AS15 ASCI when administered in combination with lapatinib. This study is for patients with metastatic breast cancer (invasive breast cancer with stage IV disease) that overexpresses HER2 and is resistant to trastuzumab (Herceptin).</p> <p>The dHER2 + AS15 candidate Antigen-Specific Cancer Immunotherapeutic (ASCI) contains a recombinant protein termed dHER2, which is a truncated version of the HER2 protein. HER2 is a protein that is commonly overexpressed in breast cancer. This protein is combined with the immunological adjuvant AS15 Adjuvant System from GSK (GlaxoSmithKline), which is a liposomal formulation containing three immunostimulatory components.</p> <p>Lapatinib is FDA approved for use in combination with capecitabine for the treatment of subjects with advanced or metastatic breast cancer overexpress HER2.</p> | |
| Recruiting | <p>Evaluation of a New Anti-cancer Vaccine for Patients With Non-small Cell Lung Cancer, After Tumor Removal by Surgery</p> <p>Conditions: Non-Small Cell Lung Cancer; Lung Cancer, Non-Small Cell</p> <p>Intervention: Biological: Immunotherapeutic GSK2302032A, different formulations 2009</p> | Immunotherapeutic GSK2302032A, different formulations : |
| | <p>[Purpose] This is a phase I/II study to determine the safety and gain insight into the immune response of the immunologic agent dHER2+AS15 ASCI when administered in combination with lapatinib. This study is for patients with metastatic breast cancer (invasive breast cancer with stage IV disease) that overexpresses HER2 and is resistant to trastuzumab (Herceptin).</p> <p>The dHER2 + AS15 candidate Antigen-Specific Cancer Immunotherapeutic (ASCI) contains a recombinant protein termed dHER2, which is a truncated version of the HER2 protein. HER2 is a protein that is commonly overexpressed in breast cancer. This protein is combined with the immunological adjuvant AS15 Adjuvant System from GSK (GlaxoSmithKline), which is a liposomal formulation containing three immunostimulatory components.</p> <p>Lapatinib is FDA approved for use in combination with capecitabine for the treatment of tumors overexpress HER2.</p> <p>Primary : The safety of dHER2+AS15 ASCI when administered in combination with Lapatinib measured by dose limiting toxicity. [Time Frame: 26 weeks]</p> <p>Secondary: The specific humoral and cellular immune response induced by the dHER2+AS15 ASCI upon co-administration of Lapatinib [Time Frame: 26 weeks]</p> | |
| Active, not recruiting | <p>Trial to Compare the Routes of Administration of an Investigational, Personalized, Therapeutic Cancer Vaccine Oncophage (HSPPC-96) in Patients With Metastatic Renal Cell Carcinoma</p> <p>Condition: Renal Cell Carcinoma</p> <p>Intervention: Biological: autologous human tumor-derived HSPPC-96 2004</p> | autologous human tumor-derived HSPPC-96. Oncophage (HSPPC-96) in Patients With Metastatic Renal Cell Carcinoma |
| | <p>Detailed: The goal of this trial is to determine the safety of HSPPC-96 and which route of administration achieves a better response with the vaccine. HSPPC-96 is an immunotherapeutic agent made from an individual patient's tumor. The study is being conducted in Houston, Texas with patients enrolled into one of two treatment arms. The two treatment arms are either subcutaneous injection or intradermal injection, both with HSPPC-96. To be treated with HSPPC-96 patients must undergo surgery to remove the kidney tumor and a portion of this tissue will be sent to Antigenics' manufacturing facility for processing</p> | |
| Active, not recruiting | <p>Study of Repeat Intranodal Injection of Memgen's Cancer Vaccine, Ad-ISF35, in Subjects With Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)</p> <p>Conditions: Chronic Lymphocytic Leukemia; Small Lymphocytic Lymphoma</p> <p>Intervention: Biological: ISF35 2009</p> | ISF35 : Adenovirus-CD 154 (Ad-ISF35) in Patients With CLL/ SLL. ISF35 is an abbreviation for Immune Stimulatory Factor 35 |

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| | <p>Primary]: Determine and monitor clinical and biological responses in patients treated with repeat intranodal injections of Ad-ISF35. [Time Frame: 2 years (evaluation will be approx. 4 months per patient)]</p> <p>Secondary] : Determine the safety of repeat administration of Ad-ISF35 injected directly into lymph nodes of patients with CLL/SLL. [Time Frame: 2 years (evaluation will be approx. 1 year per patient)] /Determine pharmacodynamic parameters in patients treated with repeat intranodal injections of Ad-ISF35. [Time Frame: 2 years (evaluation will be approx. 4 months per patient)]</p> <p>[Detailed] : This is a phase II clinical trial in which study subjects will be treated with multiple doses of Ad-ISF35 given via intranodal injection using a fixed dose of 3.3×10^{10} ISF35 viral particles. Intranodal injections will be administered every 2-4 weeks up to six total injections. Because this is the first time that repeat administration of Ad-ISF35 will be performed via intranodal injection, and in order to allow sufficient time to evaluate the safety and toxicity of this procedure, we will treat subjects 1 thru 3 at one month intervals and with inpatient admission for 24 hours observation. After subject three receives their second ISF35 injection we will proceed with enrollment of cohorts of four patients per month at one week intervals until study enrollment has been completed. These subjects will be treated as outpatients and will be observed for 3 hours prior to discharge. ISF35 has already been used in Phase I clinical trials. The trials demonstrated that ISF35 treatment is well-tolerated and patients did not experience any significant or unexpected adverse events. Patients reported flu-like symptoms from ISF35, which disappeared within one to three days</p> | |
| Active, not recruiting | <p>A Dose-Escalation Vaccine Trial In HER2-Overexpressing Patients With High-Risk Breast Cancer</p> <p>Condition: Breast Cancer</p> <p>Intervention: Biological: Investigational Cancer Vaccine 2003</p> | <p>dHER2 Protein With AS15 Adjuvant in HER2-Overexpressing Patients With High-Risk Breast Cancer</p> |
| | <p>Purpose] This trial will test how safe this vaccine is. It also tests whether its introduction induces an immune response by stimulating the patient's own immune system to recognize a specific target molecule called HER2, which is overexpressed in many breast cancers. The vaccine in this trial has not previously been administered to humans, and therefore the induction of the desired immune responses in humans remains to be established. Patients will receive 6 intramuscular vaccinations over a 14 week period, with 9 clinic visits and 3 follow up visits. In addition, patients are asked to revisit the study physician once a year for 5 years after the study ends to evaluate any long-term effects.</p> | |
| Completed | <p>Vaccine Therapy and Biological Therapy in Treating Patients With Advanced Cancer</p> <p>Conditions: Breast Cancer; Cervical Cancer; Colorectal Cancer; Lung Cancer; Ovarian Cancer; Pancreatic Cancer</p> <p>Interventions: Biological: aldesleukin; Biological: mutant p53 peptide pulsed dendritic cell vaccine; Biological: ras peptide cancer vaccine; Biological: sargramostim; Biological: therapeutic autologous lymphocytes; Biological: therapeutic tumor infiltrating lymphocytes</p> | <p>Biological: aldesleukin</p> <p>Biological: mutant p53 peptide pulsed dendritic cell vaccine</p> <p>Biological: ras peptide cancer vaccine</p> <p>Biological: sargramostim</p> |
| | <p>OBJECTIVES: I. Determine whether endogenous cellular immunity to a particular tumor-specific mutated p53 or ras protein is present in patients with tumors expressing mutant p53 or ras. II. Determine whether vaccination with antigen-presenting cells pulsed in vitro with synthetic peptide corresponding to the tumor's p53 or ras mutation in the presence of sargramostim (GM-CSF) can induce or boost patient cellular immunity to the mutated peptide in this patient population. III. Assess the type and characteristics of the cellular immunity generated. IV. Determine whether in vivo-primed T-cells generated against the p53 or ras mutation, expanded in vitro with corresponding peptide, and infused with subcutaneous interleukin-2 can enhance the activity of specific cytotoxic T-lymphocyte immune response and/or tumor response in these patients.</p> | |
| Completed | <p>Vaccine Therapy Plus Biological Therapy in Treating Adults With Metastatic Solid Tumors</p> <p>Conditions: Colorectal Cancer; Endometrial Cancer; Head and Neck Cancer; Liver Cancer; Lung Cancer; Melanoma (Skin); Pancreatic Cancer; Testicular Germ Cell Tumor; Unspecified Adult Solid Tumor, Protocol Specific</p> <p>Interventions: Biological: aldesleukin; Biological: ras peptide cancer vaccine; Biological: sargramostim; Drug: DetoxPC</p> | <p>Biological: aldesleukin</p> <p>Biological: ras peptide cancer vaccine</p> <p>Biological: sargramostim</p> <p>Drug: DetoxPC</p> |

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| | <p>OBJECTIVES: Determine whether endogenous cellular immunity to a tumor-specific mutated ras protein is present in cancer patients. Determine whether vaccination with synthetic peptides corresponding to the tumor's ras mutation with DetoxPC adjuvant, interleukin-2 (IL-2), and/or sargramostim (GM-CSF) can induce or boost a patient's cellular immunity to that particular mutation. Determine the type and characteristics of the cellular immune response generated. Determine the tolerance to and toxicity spectrum of such peptides given with DetoxPC adjuvant along with IL-2 and/or GM-CSF. Correlate immune response with tumor response in patients treated with these regimens.</p> <p>OUTLINE: Patients are assigned to one of three treatment groups.</p> <p>Group I (closed to accrual 6/4/01): Patients receive tumor-specific ras peptide vaccine with DetoxPC subcutaneously (SC) once every 5 weeks for 3 courses. Beginning 4 days after vaccination, patients receive interleukin-2 (IL-2) SC 5 days a week for 2 weeks.</p> <p>Group II (closed to accrual 6/4/01): Patients receive sargramostim (GM-CSF) SC daily beginning 1 day prior to the vaccination and continuing for 4 days. Patients receive the vaccination as in group I immediately followed by GM-CSF on day 2. Patients are vaccinated once every 4 weeks for 3 courses.</p> <p>Group III: Patients receive the vaccination and IL-2 as in group I and GM-CSF as in group II.</p> <p>In all groups, patients receive up to 15 vaccinations in the absence of disease progression. Patients are followed every 2 months.</p> | | | | | | |
| Completed | <p>Vaccine Therapy in Treating Patients With Colon, Pancreatic, or Lung Cancer</p> <table border="1"> <tr> <td>Conditions:</td> <td>Recurrent Colon Cancer; Extensive Stage Small Cell Lung Cancer; Stage III Pancreatic Cancer; Stage III Rectal Cancer; Limited Stage Small Cell Lung Cancer; Recurrent Pancreatic Cancer; Recurrent Rectal Cancer; Stage III Non-Small Cell Lung Cancer; Stage I Pancreatic Cancer; Stage II Non-Small Cell Lung Cancer; Stage IVB Pancreatic Cancer; Stage II Pancreatic Cancer; Stage III Colon Cancer; Stage IVA</td> <td rowspan="2">Drug: Detox-B adjuvant Drug: ras peptide cancer vaccine</td> </tr> <tr> <td>Interventions:</td> <td>Drug: Detox-B adjuvant; Drug: ras peptide cancer vaccine</td> </tr> </table> | | Conditions: | Recurrent Colon Cancer; Extensive Stage Small Cell Lung Cancer; Stage III Pancreatic Cancer; Stage III Rectal Cancer; Limited Stage Small Cell Lung Cancer; Recurrent Pancreatic Cancer; Recurrent Rectal Cancer; Stage III Non-Small Cell Lung Cancer; Stage I Pancreatic Cancer; Stage II Non-Small Cell Lung Cancer; Stage IVB Pancreatic Cancer; Stage II Pancreatic Cancer; Stage III Colon Cancer; Stage IVA | Drug: Detox-B adjuvant Drug: ras peptide cancer vaccine | Interventions: | Drug: Detox-B adjuvant; Drug: ras peptide cancer vaccine |
| Conditions: | Recurrent Colon Cancer; Extensive Stage Small Cell Lung Cancer; Stage III Pancreatic Cancer; Stage III Rectal Cancer; Limited Stage Small Cell Lung Cancer; Recurrent Pancreatic Cancer; Recurrent Rectal Cancer; Stage III Non-Small Cell Lung Cancer; Stage I Pancreatic Cancer; Stage II Non-Small Cell Lung Cancer; Stage IVB Pancreatic Cancer; Stage II Pancreatic Cancer; Stage III Colon Cancer; Stage IVA | Drug: Detox-B adjuvant Drug: ras peptide cancer vaccine | | | | | |
| Interventions: | Drug: Detox-B adjuvant; Drug: ras peptide cancer vaccine | | | | | | |
| | <p>Detailed Description: OBJECTIVES: I. Determine whether endogenous cellular or humoral immunity to a tumor-specific mutated ras protein is present in patients with colorectal, pancreatic, or lung cancer.</p> <p>II. Determine whether vaccination with a synthetic peptide corresponding to the tumor's ras mutation combined with Detox-B adjuvant can induce or boost cellular immunity to that particular mutation in this patient population.</p> <p>III. Determine the type and characteristics of any cellular immunity generated in these patients treated with this regimen.</p> <p>IV. Determine the tolerance and toxicity spectra of such peptides given with Detox-B adjuvant in these patients.</p> <p>V. Determine the immune response associated with each peptide dose in these patients.</p> <p>VI. Assess any tumor response that may occur with treatment in these patients treated with this regimen.</p> <p>PROTOCOL OUTLINE: This is a dose-escalation study. Patients receive tumor-specific mutated ras peptide combined with Detox-B adjuvant subcutaneously monthly for 3 months. Treatment continues in the absence of disease progression or unacceptable toxicity. Patients with stable or responding disease or with a specific immunologic response may receive 3 additional monthly vaccinations.</p> <p>Cohorts of 3-6 patients receive escalating doses of tumor-specific mutated ras peptide combined with Detox-B adjuvant 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.</p> | | | | | | |
| Completed | <p>Vaccine Therapy Plus QS21 in Treating Patients With Advanced Pancreatic or Colorectal Cancer</p> <table border="1"> <tr> <td>Conditions:</td> <td>Colorectal Cancer; Pancreatic Cancer</td> <td rowspan="2">Biological: QS21 Biological: ras peptide cancer vaccine</td> </tr> <tr> <td>Interventions:</td> <td>Biological: QS21; Biological: ras peptide cancer vaccine</td> </tr> </table> | | Conditions: | Colorectal Cancer; Pancreatic Cancer | Biological: QS21 Biological: ras peptide cancer vaccine | Interventions: | Biological: QS21; Biological: ras peptide cancer vaccine |
| Conditions: | Colorectal Cancer; Pancreatic Cancer | Biological: QS21 Biological: ras peptide cancer vaccine | | | | | |
| Interventions: | Biological: QS21; Biological: ras peptide cancer vaccine | | | | | | |

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| | <p>Detailed Description: OBJECTIVES: I. Determine the toxicity of ras peptide cancer vaccine plus immunological adjuvant QS21 in patients with advanced pancreatic or colorectal adenocarcinoma. II. Determine the immunologic effects of this treatment regimen in these patients. III. Determine the antitumor effect of this treatment regimen in these patients.</p> <p>OUTLINE: This is a dose escalation study of ras peptide cancer vaccine. Patients receive ras peptide cancer vaccine mixed with immunological adjuvant QS21 subcutaneously monthly for 4 doses, every 2 months for 4 doses, every 4 months for 3 doses, every 6 months for 2 doses, and then annually thereafter in the absence of unacceptable toxicity. Cohorts of 3 to 6 patients receive escalating doses of ras peptide cancer vaccine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which at least 2 of 3 or 2 of 4 patients experience dose limiting toxicity.</p> <p>PROJECTED ACCRUAL: Approximately 15-20 patients will be accrued for this study within 30 months.</p> | |
| Completed | <p>Vaccine Therapy With or Without Interleukin-2 in Treating Patients With Locally Advanced or Metastatic Colorectal Cancer</p> <p>Condition: Colorectal Cancer 2001</p> <p>Interventions: Biological: aldesleukin; Biological: ras peptide cancer vaccine; Procedure: adjuvant therapy</p> | <p>Biological: aldesleukin</p> <p>Biological: ras peptide cancer vaccine</p> <p>Procedure: adjuvant therapy</p> |
| | <p>Primary : Response rate every 3 months for up to a year after completion of study treatment</p> <p>OBJECTIVES: Determine the frequency of immunologic response in patients with locally advanced or metastatic colorectal cancer treated with ras peptide-pulsed dendritic cell vaccine with or without interleukin-2.</p> <p>Determine the tumor response and survival time in patients with metastatic colorectal cancer treated with vaccine plus interleukin-2.</p> <p>Determine the time to progression in patients with locally advanced colorectal cancer treated with adjuvant vaccine.</p> <p>OUTLINE: Patients are assigned to 1 of 2 treatment groups according to extent of disease. Patients with prior locally advanced disease are assigned to treatment group A, while those with metastatic disease are assigned to treatment group B.</p> <p>Group A: Patients are vaccinated against influenza on day -6. Patients undergo collection of peripheral blood mononuclear cells (PBMC) on day -4. The PBMC are cultured with sargramostim (GM-CSF) and interleukin-4 for 5 days and CD40 ligand for 24 hours and then pulsed for 2 hours with the appropriate peptide to form a vaccine. Patients receive ras peptide-pulsed dendritic cell vaccine IV over 5 minutes on days 1, 15, 29, 43, and 57.</p> <p>Group B: Patients undergo collection of PBMC and receive vaccination as in group A. Patients also receive interleukin-2 subcutaneously on days 2-6 and 9-13. Treatment in both groups repeats every 2 weeks for up to 5 vaccinations in the absence of disease progression or unacceptable toxicity.</p> | |
| Active, not recruiting | <p>Vaccine Therapy Plus Interleukin-12 in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy</p> <p>Condition: Prostate Cancer</p> <p>Interventions: Biological: PSA prostate cancer vaccine; Biological: recombinant interleukin-12</p> | <p>Biological: PSA prostate cancer vaccine + recombinant interleukin-12</p> <p>PSMA Peptide-Pulsed Autologous PBMC Plus rhIL-12</p> |

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| | <p>Purpose RATIONALE: Vaccines made from a patient's white blood cells may make the body build an immune response to kill cancer cells. Interleukin-12 may kill cancer cells by stopping blood flow to the tumor and by stimulating a person's white blood cells to kill cancer cells. Combining vaccine therapy with interleukin-12 may kill more tumor cells.</p> <p>PURPOSE: Phase II trial to study the effectiveness of vaccine therapy combined with interleukin-12 in treating patients who have metastatic prostate cancer that has not responded to hormone therapy</p> <p>OBJECTIVES: Determine whether immunization with prostate-specific membrane antigen-pulsed autologous peripheral blood mononuclear cells and interleukin-12 can promote specific T-cell priming in patients with metastatic hormone-refractory prostate cancer.</p> <p>Determine the clinical response in patients treated with this regimen.</p> <p>OUTLINE: Patients receive prostate-specific membrane antigen-pulsed autologous peripheral blood mononuclear cells subcutaneously (SC) on day 1 and interleukin-12 SC on days 1, 3, and 5. Treatment repeats every 21 days for 3-9 courses in the absence of disease progression or unacceptable toxicity.</p> | | | | | |
| Completed | <p>Vaccine Therapy Combined With Adjuvant Chemoradiotherapy in Treating Patients With Resected Stage I or Stage II Adenocarcinoma (Cancer) of the Pancreas</p> <table border="1"> <tr> <td>Condition:</td> <td>Pancreatic Cancer</td> </tr> <tr> <td>Interventions:</td> <td>Biological: GVAX pancreatic cancer vaccine; Drug: fluorouracil; Procedure: adjuvant therapy; Radiation: radiation therapy 2004</td> </tr> </table> | Condition: | Pancreatic Cancer | Interventions: | Biological: GVAX pancreatic cancer vaccine; Drug: fluorouracil; Procedure: adjuvant therapy; Radiation: radiation therapy 2004 | <p>GVAX pancreatic cancer vaccine + fluorouracil + adjuvant therapy mesothelin-specific T-cell response</p> |
| Condition: | Pancreatic Cancer | | | | | |
| Interventions: | Biological: GVAX pancreatic cancer vaccine; Drug: fluorouracil; Procedure: adjuvant therapy; Radiation: radiation therapy 2004 | | | | | |
| | <p>RATIONALE: Vaccines made from gene-modified pancreatic cancer cells may make the body build an immune response to kill tumor cells. Drugs used in chemotherapy, such as fluorouracil, work in different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage tumor cells. Giving vaccine therapy together with chemotherapy and radiation therapy after surgery may kill any remaining tumor cells.</p> <p>Primary: Determine overall and disease-free survival of patients with resected stage I or II adenocarcinoma of the pancreas treated with adjuvant chemoradiotherapy in combination with GVAX pancreatic cancer vaccine.</p> <p>Secondary: Correlate specific in vivo parameters of immune response (post-vaccination delayed-type hypersensitivity reactions to autologous tumor, mesothelin-specific T-cell response, and the degree of local eosinophil, macrophage, and T-cell infiltration at the vaccine site) with clinical responses in patients treated with this regimen.</p> <p>Determine the toxic effects associated with intradermal injections of this vaccine in these patients.</p> <p>OUTLINE: This is an open-label study.</p> <p>Post surgery vaccination: Within 8-10 weeks after pancreaticoduodenectomy, patients receive GVAX pancreatic cancer vaccine intradermally (ID) on day 0.</p> <p>Adjuvant chemoradiotherapy: Within 16-28 days after the first vaccination, patients receive fluorouracil (5-FU) IV continuously for 3 weeks. Approximately 1-2 weeks after completion of 5-FU, patients receive chemoradiotherapy comprising radiotherapy daily and 5-FU IV continuously for 26-28 weeks. Approximately 3-5 weeks after completion of chemoradiotherapy, patients receive 5-FU IV continuously for 4 weeks. 5-FU repeats every 6 weeks for 2 courses.</p> <p>Post chemoradiotherapy vaccination: Within 4-8 weeks after the completion of chemoradiotherapy, patients receive GVAX pancreatic cancer vaccine ID on days 0, 28, 56, and 196.</p> | | | | | |
| Active, not recruiting | <p>Vaccine Therapy in Treating Patients With Recurrent Prostate Cancer</p> <table border="1"> <tr> <td>Condition:</td> <td>Prostate Cancer</td> </tr> <tr> <td>Interventions:</td> <td>Biological: PSA prostate cancer vaccine; Biological: incomplete Freund's adjuvant 2002</td> </tr> </table> | Condition: | Prostate Cancer | Interventions: | Biological: PSA prostate cancer vaccine; Biological: incomplete Freund's adjuvant 2002 | <p>PSA prostate cancer vaccine + incomplete Freund's adjuvant. Prostate Specific Antigen-3 (PSA-3) With Montanide</p> |
| Condition: | Prostate Cancer | | | | | |
| Interventions: | Biological: PSA prostate cancer vaccine; Biological: incomplete Freund's adjuvant 2002 | | | | | |

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| | <p>Detailed Description: OBJECTIVES: I. Determine the effect of PSA-3 peptide vaccine emulsified in Montanide ISA-51 on PSA levels in patients with recurrent prostate cancer. II. Determine the toxicity of this regimen in these patients. III. Determine whether the T lymphocyte immune response to PSA-3 and HLA-A2 antigen-presenting cells that endogenously produce PSA is increased in patients treated with this regimen. IV. Determine the duration of the PSA and/or immune responses in patients treated with this regimen. V. Correlate immune and PSA responses in patients treated with this regimen. VI. Determine the efficacy of a second (boost) vaccination with this regimen in patients with a PSA or immune response.</p> <p>OUTLINE: This is a multicenter study. Patients receive PSA-3 peptide vaccine emulsified in Montanide ISA-51 subcutaneously in 2 sites on days 1, 8, 15, and 22 in the absence of unacceptable toxicity. Patients who show an immune or prostate specific antigen (PSA) response are followed until disease progression, defined as a diminution or disappearance of an immune response or 2 consecutive increases in PSA over the nadir. Patients are eligible for a second series of injections at the time of progression.</p> <p>PROJECTED ACCRUAL: A total of 14-44 patients will be accrued for this study within 12-18 months.</p> | |
| Completed | <p>Vaccine Therapy and Sargramostim in Treating Patients With Non-Small Cell Lung Cancer</p> <p>Condition: Lung Cancer</p> <p>Interventions: Biological: ras peptide cancer vaccine; Biological: sargramostim 2000</p> | <p>ras peptide cancer vaccine + sargramostim (GM-CSF)</p> |
| | <p>OBJECTIVES: Determine whether a specific T-cell response can be induced in patients with stage IB-IV non-small cell lung cancer treated with mutant K-ras peptide vaccine (limited to the specific K-ras peptide mutation in their tumors) and sargramostim (GM-CSF). Determine whether skin test reactivity or HLA type correlates with the induction of anti-K-ras immune responses in patients treated with this regimen. Determine the toxicity of this regimen in these patients.</p> <p>OUTLINE: Patients receive sargramostim (GM-CSF) intradermally (ID) on days 1-10 beginning a maximum of 6 months after complete surgical resection. Patients receive mutant K-ras peptide vaccine (limited to the specific K-ras mutation in their tumors) ID on day 7. Treatment repeats every 4 weeks for 3 courses in the absence of disease progression or unacceptable toxicity. Patients are followed at 4 and 12 weeks.</p> | |
| Active, not recruiting | <p>Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy</p> <p>Condition: Prostate Cancer</p> <p>Interventions: Biological: PSA prostate cancer vaccine; Biological: therapeutic autologous dendritic cells 2000</p> | <p>PSA prostate cancer vaccine (rPSMA) +: therapeutic autologous dendritic cells.</p> |
| | <p>OBJECTIVES: I. Assess the safety of recombinant prostate-specific membrane antigen (rPSMA)-pulsed autologous dendritic cells (CaPVax) in patients with metastatic hormone-refractory prostate cancer. II. Determine the potential clinical response in patients treated with this regimen. III. Determine the effect of this treatment regimen on pain, physical function, and quality of life of these patients.</p> <p>OUTLINE: This is a dose-escalation, multicenter study. Patients undergo a delayed hypersensitivity skin test with 3 common recall antigens. Autologous dendritic cells (DC) are pulsed with recombinant prostate-specific membrane antigen (rPSMA). Patients receive rPSMA-pulsed autologous DC (CaPVax) intradermally. Treatment repeats every 4 weeks for a total of 4 courses in the absence of disease progression or unacceptable toxicity. Cohorts of 3-6 patients receive escalating doses of CaPVax 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. Quality of life questionnaires are completed five times over the course of the study. Patients are followed at 3 months.</p> <p>PROJECTED ACCRUAL: A total of 60 patients will be accrued for this study.</p> | |
| Completed | <p>Vaccine Therapy in Treating Patients With Myelodysplastic Syndrome</p> <p>Conditions: Leukemia; Myelodysplastic Syndromes</p> <p>Interventions: Biological: ras peptide cancer vaccine; Biological: sargramostim 2000</p> | <p>ras peptide cancer vaccine + sargramostim (GM-CSF)</p> |

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| | <p>OBJECTIVES: I. Determine whether a specific T-cell response can be induced in patients with myelodysplastic syndrome treated with mutant N-, K-, or H-ras peptide vaccine (limited to the specific N-, K-, or H-ras peptide mutation in their bone marrow) and intradermal sargramostim (GM-CSF). II. Determine whether HLA type or the ability to respond immunologically to common recall antigens correlates with the induction of anti-ras immune responses in these patients treated with this regimen. III. Assess toxicity of mutant N-, K-, or H-ras peptide vaccine in these patients.</p> <p>OUTLINE: Patients receive sargramostim (GM-CSF) intradermally on days 1-10. Patients receive mutant N-, K-, or H-ras peptide vaccine (limited to the specific N-, K-, or H-ras mutation in their bone marrow) intradermally on day 7. Treatment repeats every 4 weeks for up to 5 courses in the absence of disease progression or unacceptable toxicity. Patients are followed at 2 and 6 weeks after the last vaccination.</p> <p>PROJECTED ACCRUAL: A total of 25-70 patients will be accrued for this study over 12-15 months.</p> | | | |
| Completed | <p>Vaccine Therapy in Treating Women With Metastatic Breast Cancer</p> | | CD80-Modified Allogeneic Breast Cancer Cell Line to Vaccinate HLA-A2-Positive. CD80-transfected MDA-MB-231. | |
| | Condition: | Breast Cancer | | |
| | Interventions: | Biological: BCG vaccine; Biological: CD80 breast cancer vaccine; Biological: sargramostim 1999 | | |
| | <p>OBJECTIVES: Determine the safety and toxicity of vaccination strategies employing a CD80-transfected allogeneic breast cancer cell line (MDA-MB-231). Assess the immunologic response of lymphocytes isolated from lymph nodes draining the vaccination site following a single dose of CD80-transfected MDA-MB-231. Assess the development of systemic immunity following multiple injections of CD80-transfected MDA-MB-231. Observe for tumor regression.</p> <p>OUTLINE: This is a dose-escalation study. Patients receive intradermal vaccinations containing CD80-transfected cells with or without sargramostim (GM-CSF) or with or without BCG. Vaccinations are administered every 2 weeks for 6 weeks and then monthly for 3 months. Patients may receive 1 of 2 different doses of GM-CSF. GM-CSF is administered with the vaccination, then every 12 hours for 7 days. Monthly vaccinations may continue as long as response is shown. Cohorts of 5 patients each are treated at each dose/combination. Each cohort completes treatment before the next cohort is accrued. Patients are followed at weeks 4 and 8, then every 2 months for 6 months, then every 3 months for 1 year, and then every 6 months until disease progression.</p> | | | |
| Active, not recruiting | <p>Study of Repeat Intranodal Injection of Memgen's Cancer Vaccine, Ad-ISF35, in Subjects With Non-Hodgkin's Lymphoma (Follicular, Diffuse Large Cell, Mantle Cell, and Small Lymphocytic Lymphoma/Chronic Lymphocytic Leukemia)</p> | | ISF35 : Adenovirus-CD154 (Ad-ISF35) in Patients With Non-Hodgkin's Lymphoma etc. | |
| | Conditions: | Non-Hodgkin's Lymphoma; Follicular Lymphoma; Diffuse Large Cell Lymphoma; Mantle Cell Lymphoma; Small Lymphocytic Lymphoma; Chronic Lymphocytic Leukemia | | |
| | Intervention: | Biological: ISF35 2009 | | |