Autologous Bone Marrow

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Emory University	5982	CD34 Positive selection of autologous bone marrow in poor risk non-Hodgkin's lymphoma with the CEPRATE SC Concentrator and the FACS Vantage: a pilot trial	Holland
MD Anderson Cancer Center		Cyclophosphamide, VP-16, and Total Body Irradiation followed by Bone Marrow Transplantation with Autologous Cells in Patients with Accelerated Phase or Blast Crisis Myelogenous Leukemia: A Pilot Trial	Deisseroth
	5879	Bone Marrow Transplantation for Chronic Lymphocytic Leukemia	Champlin
	5879	Autologous bone marrow transplantation using ex vivo selection for low grade lymphoma	Champlin
University of Pennsylvania	4297	Autologous bone marrow transplantation using C-MYB (LR3001) antisense oligodeoxynucleotide treated bone marrow in chronic myelogenous leukemia in chronic or accelerated phase	Gewirtz

Report Summary

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Autologous PBPC

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Bowman Gray School of Medicine	6179	Phase II trial of high dose cytoxan, VP-16, carboplatin (CBDCA) and total body irradiation with CEPRATE selected CD34+ peripheral blood progenitor cells in patients with non-hodgkins lymphoma	Hurd
Children's Hospital - Boston	6244	Double dose intensive chemo-radiotherapy with peripheral blood progenitor cell rescue for children with advanced stage neuroblastoma and sarcomas	Gorlin
City of Hope National Medical Center	4906	High-dose chemotherapy followed by reinfusion of peripherally-derived stem cell products enriched in CD34+ cells. A pilot study to evaluate the safety and efficacy of immunoadsorption for positive selection of early hematopoietic cells	Somlo
Dana Farber Cancer Institute	5928	A Phase II study of high dose cyclophosphamide, cisplatin and carmustine (CBP) therapy as consolidation for patients with limited small cell lung cancer (SCLC) in partial or complete response to chemo(radio)therapy: Use of CD34+ selected PBPC as support	Elias
Fred Hutchinson Cancer Research Center	5915	A pilot study of total body irradiation and cyclophosphamide followed by autologous transplantation with CD34 selected peripheral blood stem cells in patients with chronic lymphocytic leukemia	McSweeney
Medical College of Virginia	6179	Phase II trial of high dose cytoxan, VP-16, carboplatin (CBDCA) and total body irradiation with CEPRATE selected CD34+ peripheral blood progenitor cells in patients with non-hodgkins lymphoma	Yanovich
Memorial Sloan-Kettering	5181	Evaluation of Positively Selected Peripheral Blood Progenitors as Hematopoietic Rescue Following Sequential Thiotepa in Patients with Metastatic Breast Cancer	Raptis

Autologous PBPC

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Response Oncology (Impact Centers of Nashville, Grand Rapids and Hampton Roads)	6187	Treatment of low grade non-Hodgkin's lymphoma with BEAC followed by hematopoietic reconstitution with CD34+ selected peripheral blood progenitor cells harvested during remission	Weaver
	6187	A randomized phase II pilot eval. of engraftment comparing the kinetics of unselected and selected CD34+ PBPC's following the administration of high dose cyclophosphamide, thiotepa and carboplatin for the treatment of stage IV breast cancer	Weaver
St Louis University Medical Center	5096	Transplantation of Autologous Peripheral CD34+ Stem Cells as Treatment for Multiple Myeloma: A Multi-Institutional Trial	Spitzer
UCLA	5096	Transplantation of Autologous Peripheral CD34+ Stem Cells as Treatment for Multiple Myeloma: A Multi-Institutional Trial	Berenson
Univ. of Colorado Health Sciences Center	4495	A Phase I Study Using CellPro Stem Cell Concentrator to Concentrate Hematopoietic Progenitors for Use in Autologous Bone Marrow Transplantation	Shpall
	5096	Transplantation of Autologous Peripheral CD34+ Stem Cells as Treatment for Multiple Myeloma: A Multi-Institutional Trial	Bearman
University Hospital of Cleveland	5991	A Phase II trial using CEPRATE SC Stem Cell Concentrator in peripheral blood progenitor cell transplantation for lymphoma	Lazarus
University of Kentucky	5991	A Phase II trial using CEPRATE SC Stem Cell Concentrator in peripheral blood progenitor cell transplantation for lymphoma	Phillips
University of North Carolina	6179	Phase II trial of high dose cytoxan, VP-16, carboplatin (CBDCA) and total body irradiation with CEPRATE selected CD34+ peripheral blood progenitor cells in patients with non-hodgkins lymphoma	Shea

Autologous PBPC

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
University of Texas Health Sciences Center	5096	Transplantation of Autologous Peripheral CD34+ Stem Cells as Treatment for Multiple Myeloma: A Multi-Institutional Trial	Freytes
Washington University	6179	Phase II trial of high dose cytoxan, VP-16, carboplatin (CBDCA) and total body irradiation with CEPRATE selected CD34+ peripheral blood progenitor cells in patients with non-hodgkins lymphoma	DiPersio

Report Summary

18 Sites **11 Protocols** **17 Investigators**

Allogeneic

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Johns Hopkins University	4683	Augmenting Lymphocyte Dose Modified Bone Marrow with CD34+ Hematopoietic Progenitor Cells to Improve Allogeneic Donor Engraftment	Noga
	5538	Combination Elutriation Plus GVHD Prophylaxis Using Cyclosporine in High Risk Mismatched and Unrelated Transplants	Noga
	5728	GM-CSF (rhu-GM-CSF) for reduction of leukemic relapse after T-lymphocyte depleted allogeneic BMT for chronic myeloid leukemia	Jones
MD Anderson Cancer Center	5879	Allogeneic Transplantation of CD34 Selected Blood and Bone Marrow Cells in Patients with Leukemia	Gajewski
Memorial Sloan-Kettering	Pending	Ph II; T-cell depleted marrow combined w/ infusions of G-CSF stimulated CD34 CEPRATE SC column selected, E-rosetted depleted PBSC's derived fr HLA haplotype matched related donors for patients w/ leukemia lacking HLA-matched related or unrelated donors	O'Reilly
University of Minnesota	5582	Transplantation of Non-Genotypic Identical Marrow in Patients with Fanconi Anemia (MT9510)	Wagner
	5582	A Phase I trial in the Use of CD34+ Stem Cells and Unrelated Donor Bone Marrow Depleted of Lymphocytes by Counterflow Elutriation (MT9327)	Wagner
	5976	Randomized Trial to Determine the Impact of T Cell Depletion by Counterflow Elutriation and CD34 Add-back in Unrelated Donor Marrow Transplantation	Wagner
University of Nebraska Medical Center	5976	Randomized Trial to Determine the Impact of T Cell Depletion by Counterflow Elutriation and CD34 Add-back in Unrelated Donor Marrow Transplantation	Bishop

Allogeneic

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
University of Pittsburgh	5976	Randomized Trial to Determine the Impact of T Cell Depletion by Counterflow Elutriation and CD34 Add-back in Unrelated Donor Marrow Transplantation	Donnenberg

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Gene Therapy/Gene Marking

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Children's Hospital of LA	5056	Treatment of Severe Combined Immunodeficiency Disease (SCID) Due to Adenosine Deaminase (ADA) Deficiency with CD34+ Selected Umbilical Cord Blood Cells Transduced with a Human ADA Gene	Kohn
	5376	Retroviral Mediated Transfer of the cDNA for Human Glucocerebrosidase into Hematopoietic Stem Cells of Patients with Gaucher Disease	Kohn
Columbia University	5368	Human Multiple Drug Resistance (MDR) Gene Transfer and Expression in CD34+ Bone Marrow Cells of Patients with Advanced Breast Cancer, Ovarian Cancer and Brain Tumors who Undergo High Dose Chemotherapy and Autologous Bone Marrow Transplant	Hesdorffer
Fred Hutchinson Cancer Research Center	5173	Study on Contribution of Genetically Marked Peripheral Blood Repopulating Cells to Hematopoietic Reconstitution After Transplantation	Schuening
	5852	Retrovirus-Mediated Transfer of the cDNA for Human Glucocerebrosidase into Peripheral Blood Repopulating Cells of Patients with Gaucher's Disease	Schuening
MD Anderson Cancer Center	4115	Autologous BMT for CML in Which Retroviral Markers are Used to Discriminate Between Relapse Which Arises from Systemic Disease Remaining After Preparative Therapy Versus Relapse Due to Residual Leukemia Cells in Autologous Marrow: A Pilot Trial	Deisseroth
	5781	Use of Retroviral Markers to Identify Efficacy of Purging and Origin of Relapse Following Autologous BM and Peripheral Blood Cell Transplantation in Indolent B Cell Neoplasms (follicular NHL or CLL Pts	Deisseroth
	5887	Use of Safety-Modified Retroviruses to Introduce Chemotherapy Resistance Sequences into Normal Hematopoietic Cells for Chemoprotection During the Therapy of Ovarian / Breast Cancer: A Pilot Trial	Deisseroth

Gene Therapy/Gene Marking

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
National Institutes of Health	3624	Treatment of Severe Combined Immunodeficiency Disease Due to Adenosine Deaminase Deficiency with Autologous Lymphocytes Transduced with a Human ADA Gene	Dunbar
	4686	Pilot Study of High Dose ICE (ifosfamide, carboplatin, etoposide) Chemotherapy and Autologous Bone Marrow Transplant with neoR-Transduced Bone Marrow and Peripheral Blood Stem Cells	Dunbar
	4697	High Dose Melphalan and Total Body Irradiation with Autologous Bone Marrow and Peripheral Blood Stem Cell Support Followed by Interferon for Multiple Myeloma	Dunbar
	5056	Treatment of Severe Combined Immunodeficiency Disease (SCID) Due to Adenosine Deaminase (ADA) Deficiency with CD34+ Selected Umbilical Cord Blood Cells Transduced with a Human ADA Gene	Dunbar
	5360	Retroviral Mediated Transfer of the Human Multidrug Resistance Gene (MDR-1) into Hematopoietic Stem Cells During Autologous Transplantation After Intensive chemotherapy for Metastatic Breast Cancer	Cowan
	5376	Retroviral Mediated Transfer of the cDNA for Human Glucocerebrosidase into Hematopoietic Stem Cells of Patients with Gaucher Disease	Dunbar
	6016	Retroviral Mediated Gene Transfer of the Fanconi Anemia Complementation Group C Gene to Hematopoietic Progenitors of Group C Patients	Liu
	Pending	Pilot of Induction w/ Antimetabolites f/u w/ Consolidation w/ High-Dose Single Alkylating Agents w/ PBPC support f/u w/ Intensification w/ Sequential H-Dose Paclitaxel and Doxorubicin in Pat's w/ High Rsk Breast CA and of MDR1 and NeoR gene transduction	Cowan
Norris Cancer Center	5875	High-Dose Chemotherapy and Autologous BM plus PBSC Transplantation for Patients with Lymphoma or Metastatic Breast Cancer: Use of Marker Genes to Investigate the Biology of Hematopoietic Reconstitution in Adults	Douer
St. Jude Children's Research Hospital	6025	Use of Double Marking with Retroviral Vectors to Determine Rate of Reconstitution of Untreated and Cytokine Expanded CD34+ Selected Marrow Cells in Patients Undergoing Autologous Bone Marrow Transplantation	Heslop

Gene Therapy/Gene Marking

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
University of Massachusetts Medical Center	Pending	Gene Marking with Retroviral Vectors to Study the Feasability of Stem Cell Gene Transfer and the Biology of Hematopoietic Reconstitution After Autologous Transplant in Multiple Myeloma, Chronic Myelogenous Leukemia, or Metastatic Breast Cancer	Stewart
University of Pittsburgh	6075	Gene Therapy for Gaucher Disease: Ex Vivo Gene Transfer and Autologous Transplantation of CD34+ Cells	Barranger

Report Summary

9 Sites **18 Protocols** **12 Investigators**

In Utero Allogeneic Transplantation

Protocols by Site Name as of 1/11/96

Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Children's Hospital of LA	Pending	In Utero Transplantation of Histiocompatible CD34+ Bone Marrow Cells	Parkman
Johns Hopkins University	5790	In utero bone marrow transplantation for adrenoleukodystrophy metachromatic leukodystrophy and clobold leukodystrophy using CD34 selection of donor marrow	Jones
Univ. of Colorado Health Sciences Center	6297	In Utero Transplantation for Alpha-Thalassemia and Metabolic Diseases	Quinones

Report Summary

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Other Clinical Research Trials

Protocols by Site Name as of 1/11/96

Project Name: Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Autoimmunity			
Northwestern University / Memorial Hospital	Pending	Immune Ablation and Hematopoietic Stem Cell Support in Patients with Systemic Lupus Erythematosus and High Risk Features	Burt
	Pending	Immune Ablation and Hematopoietic Stem Cell Support in Patients with Malignant Multiple Sclerosis	Burt
UCLA	Pending	Autologous CD34 Selected Peripheral Blood Progenitor Cell Transplantation for the Treatment of Severe or Life Threatening Autoimmune Disease	Vescio
High Dose Chemotherapy			
Children's Hospital of Orange County	Pending	A Phase I Study of Multi-cycle High-dose Chemotherapy and CD34+ Peripheral Blood Stem Cell Support Followed by Autologous Peripheral Stem Cell Transplantation with CD34+ Positive-selected Stem Cells in Children with High-risk Neuroblastoma	Sender
Dana Farber Cancer Institute	4944	Pilot Trial of Combination Hematopoietins (rhG-CSF(Filgrastim) and rhErythtopoietin(Epoetin alfa)) w/ CD34-selected PBPC's to Support Repetitive Delivery of Dose-Intensified Cyclophosphamide/Doxorubicin Adj. Chemotx in Pats. w/ Node+ Resected Breast CA	Demetri
National Institutes of Health	6182	New therapeutic strategies for patients with Ewing's sarcoma family of tumors, high risk rhabdomyosarcoma and neuroblastoma	Wexler

Other Clinical Research Trials

Protocols by Site Name as of 1/11/96

Project Name: Site Name:	IDE Number:	Protocol Title:	Principal Investigator:
Solid Organ Transplantation			
Fred Hutchinson Cancer Research Center	5095	Induction of allograft tolerance in renal transplant recipients with lymphoid cells and hematopoietic stem cells	Hansen
University of Washington Medical Center	Pending	A Study Evaluating the Safety and Efficacy of Stem Cell Infusion in Solid Organ Transplant Recipients for the Induction of Microchimerism and Tolerance	Marsh
Stem Cell Expansion			
University of Minnesota	Pending	Autologous Transplantation for Chronic Phase CML using Retrovirally Marked Ex Vivo Selected and Expanded Marrow derived CD34+HLA-DR- Progenitors	Verfaillie

Report Summary

8 Sites 9 Protocols 8 Investigators