

Transplant Program

Multidisciplinary Team

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ROSWELL PARK CANCER INSTITUTE

Clinical Trials & Multidisciplinary Teams 2005



Blood and Marrow Transplantation

Welcome

The BMT Program at Roswell Park

The Roswell Park Cancer Institute (RPCI) Blood and Marrow Transplant Program (BMT) was established in 1991. The program is Foundation for the Accreditation of Cellular Therapy (FACT) certified since 2002. It emphasizes clinical trial development including investigator-initiated as well as cooperative group trials. All patients are transplanted on a clinical research study. The program continues to emphasize excellence in clinical care and patient outcomes.

reduced intensity unrelated donor transplant has been increased from 60 to 75 years. These age changes were the result of the development of a reduced intensity transplant regimen that can be used safely for patients who otherwise would not have been eligible for transplant in the past.

The Lymphoma, Leukemia and Myeloma clinical programs have novel therapeutic trials that interface with

Autologous

DS 91-15 Autologous Blood and Marrow Transplantation for Hematologic Malignancy and Selected Solid Tumors

CALGB 100001 Autologous BMT Followed by Non-Myeloablative Allogeneic Transplant for Multiple Myeloma

PH 49105 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Comparative Trial of AMD3100 (240

Autologous Stem Cell Transplantation for Multiple Myeloma

Allogeneic

CALGB 109901 Minimal Ablation and Cellular Immune Therapy of Chronic Lymphocytic Leukemia, Polymorphocytic Leukemia, Low-Grade Non-Hodgkin's Lymphoma, and Mantle Cell Lymphoma With Allogeneic Donor Stem Cells

GVHD Studies

NCG 21804 (PBMTG GVH0313) A Phase II Study of Pentostatin for the Treatment of High-Risk or Refractory Chronic GVHD in Children

NCG 52505 (CTN 0101) A Randomized Double-Blind Trial of Fluconazole vs. Voriconazole for the Prevention of Invasive Fungal Infections in Allogeneic Blood and Marrow Transplant Patients

I 00703 Cellular Infusions in Patients



The RPCI Transplant Program offers a wide range of transplant-related services including cord blood transplant, reduced intensity BMT, unrelated donor BMT, case management, quality assurance program, a dedicated onsite outpatient BMT clinic adjacent to the inpatient unit and on-site blood and marrow collection and processing. A unique aspect of our program is the presence of a clinical epidemiologist who monitors all BMT patient outcomes and oversees the BMT database. This attention to patient outcomes allows the program to make adjustments in clinical services to optimize patient care.

All patients who are considered for transplant and for tissue typing for potential transplant are reviewed by the RPCI Transplant Program on a weekly basis. Patients must fulfill protocol eligibility before transplant to ensure optimal patient outcomes. Patients are evaluated and monitored from time of presentation through the entire continuum of care related to transplant not just the transplant episode. Due to a strong focus on patient outcomes, Roswell Park can offer transplant to patients who otherwise could not have undergone transplant in the past. Recent changes include decreasing the minimum age for transplant from five years to four years for our pediatric population and increasing the age for sibling allogeneic reduced intensity transplant from 70 to 75 years. The maximum age for

the Transplant Program. The RPCI Transplant Program participates in the Cancer and Leukemia Group B Cooperative Group which has opened several protocols for allogeneic transplant after failed autologous transplant, non-myeloablative allogeneic transplant for older acute myeloid leukemia (AML) patients, allogeneic transplant for multiple myeloma, autologous transplant for AML, autologous transplant for Philadelphia chromosome positive acute lymphoblastic leukemia (ALL) and autologous transplant for myeloma followed by maintenance CC 5013 therapy versus placebo. In addition, RPCI participates as an affiliate member of the NCI/NHLBI-sponsored Transplant Trials Group and has opened the trial examining the use of peripheral blood versus bone marrow for unrelated donor allogeneic transplant. RPCI also has IRB approved protocols for the collection and storage of t(9:22) chromosome negative stem cell products from CML patients for later use for auto BMT and for novel approaches to reduced intensity BMT.

The following is a list of open protocols at Roswell Park as of August 2005. New protocols are also in development.

ug/kg) Plus G-CSF (10 ug/kg) Versus G-CSF (10 ug/kg) Plus Placebo to Mobilize and Collect $> 6 \times 10^6$ CD34+Cells/kg in Multiple Myeloma Patients for Autologous Transplantation (AMD3100-3102)

NCG 25004 (COG ANHL0121) A Phase II Study of Rituximab and Ifosfamide, Carboplatin and Etoposide (ICE) Chemotherapy in Children with Recurrent/Refractory B-Cell (CD20+) Non-Hodgkin's Lymphoma and B-Cell Acute Lymphoblastic Leukemia

NCG/CALGB 01903 (CALGB 100002): Non-Myeloablative Allogeneic Hematopoietic Cell Transplantation for Patients with Disease Relapse or Myelodysplasia After Autologous Transplantation

NCG/CALGB 46405 (CALGB 100104) A Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC#703813, IND# 70166) or Placebo Following



with Recurrent or Persistent Hematologic Malignancies after Allogeneic Stem Cell Transplant. A Tracking Study.

PBSC Mobilization

NCG 21404 (BMT CTN 0201) A Phase III Randomized, Multicenter Trial Comparing G-CSF Mobilized Peripheral Blood Stem Cell with Marrow Transplantation From HLA Compatible Unrelated Donors

Mucositis

PH 45804 (20040212) Palifermin for the Reduction of Oral Mucositis in Single-Dose Evaluation (PROMISE): A Randomized, Blinded, Active-Control Trial of Palifermin (rHuKGF) to Evaluate Oral Mucositis in Subject with Hematologic Malignancies Undergoing Fractionated Total Body Irradiation (fTBI) and High Dose Chemotherapy with Autologous Peripheral Blood Progenitor Cell (PBPC)

DS 97-26 Cord Blood Transplantation for Hematologic Malignancies and Bone Marrow Failure Syndromes

RP 01-05 Non-Myeloablative Allogeneic Hematopoietic Blood Stem Cell Transplantation for Hematologic Malignancies and Aplastic Anemia

NCG/CALGB 01903 (CALGB 100002): Non-Myeloablative Allogeneic Hematopoietic Cell Transplantation for Patients with Disease Relapse or Myelodysplasia After Autologous Transplantation