Clinical Research Protocols

This list of clinical research protocols relating to high-dose therapy for breast cancer is compiled for your convenience.

Adjuvant Trials

SWOG-S9623, SWOG-9623, E-S9623 NCI HIGH-PRIORITY CLINICAL TRIAL - Phase III Randomized Study of Intensive Sequential Doxorubicin, Paclitaxel, and Cyclophosphamide vs Doxorubicin/Cyclophosphamide Followed by STAMP I or STAMP V Combination Chemotherapy With Autologous Stem Cell Rescue in Women With Primary Breast Cancer and 4-9 Involved Axillary Lymph Nodes


EST-2190, INT-0121, SWOG-9061 NCI HIGH PRIORITY CLINICAL TRIAL - Phase III Randomized Study of Adjuvant CAF (Cyclophosphamide/Doxorubicin/Fluorouracil) vs Adjuvant CAF Followed by Intensification With High-Dose Cyclophosphamide/Thiotepa Plus Autologous Stem Cell Rescue in Women With Stage II/III Breast Cancer at High Risk of Recurrence


CLB-9082, INT-0163, SWOG-9114 NCI HIGH PRIORITY CLINICAL TRIAL - Phase III Randomized Comparison of High-Dose Chemotherapy With Autologous Marrow and Peripheral Stem Cell Support vs Standard-Dose Chemotherapy Following Adjuvant Chemotherapy in Women With Stage II/IIIA Breast Cancer With at Least 10 Positive Axillary Nodes


SLUMC-8038, NCI-V95-0607 Phase II/Ii Study of Paclitaxel Added to High-Dose Carboplatin/Cyclophosphamide With Autologous Peripheral Blood Stem Cell Support for Women With High-Risk Stage II/III Breast Cancer


FHCRC-955.01, NCI-H95-0704, FHCRC-955.00 Phase II Study of Busulfan/Melphalan/Thiotepa Followed by Autologous or Syngeneic Peripheral Blood Stem Cell Rescue for High-Risk Primary Breast Cancer


CCCFU-95946, NCI-G97-1145 Phase III Trial of Filgrastim (G-CSF) Primed Autologous Bone Marrow Versus Peripheral Blood Progenitor Cells (PBPC) as Hematopoietic Support for High-Dose Cyclophosphamide, Thiotepa, and Carboplatin Therapy (CTCb) in Poor Prognosis Breast Cancer

Chairperson: James Joseph Perry. Telephone: 910-716-4464. Lead organization: Comprehensive Cancer Center of Wake Forest University, Bowman Gray School of Medicine. Age range: 18/physiologic 60.

NCI-96-C-0032F, NCI-MB-381 Phase I Pilot Study of Sequential High-Dose Chemotherapy for High-Risk Breast Cancer: Antimetabolite Induction, Followed by Alkylating Agent Consolidation With Peripheral Blood Stem Cell Support, Followed by Paclitaxel and Doxorubicin Intensification


IBCSG-15-95, EU-96021 Phase III Randomized Study of Adjuvant High-Dose Combination Chemo-therapy With Peripheral Blood Stem Cell and G-CSF Support vs Adjuvant Sequential Standard-Dose Combination Chemotherapy for Pre- and Postmenopausal Women Younger Than 66 Years With High-Risk, Operable, Stage II/III Breast Cancer


SCTN-BR9405, EU-95048 Phase III Randomized Study of Doxorubicin Induction Followed by Either Conventional Cyclophosphamide/ Methotrexate/Fluorouracil (CMF) or High-Dose Cyclophosphamide/Thiotepa With Peripheral Blood Stem Cell Rescue for Stage II/IIIA Breast Cancer


Advanced Disease Trials

E-PBT01, NCI-T90-0180D, PBT-1 NCI HIGH PRIORITY CLINICAL TRIAL - Phase III Randomized Comparison of Conventional CMF Maintenance vs High-Dose Combination Chemotherapy Plus Autologous Bone Marrow and Peripheral Stem Cell Rescue in Women With Metastatic Breast Cancer Responding to
Conventional Induction Chemotherapy


Phase II Study of Peripheral Blood Stem Cells (PBSC) or Isolated CD34+ Cells from Mobilized Peripheral Stem Cell Collections for Hematologic Rescue of Advanced Breast Cancer Patients Treated With High-Dose Chemotherapy


Phase I/II Study of Paclitaxel Added to High-Dose Carboplatin/Cyclophosphamide With Autologous Peripheral Blood Stem Cell Support for Women With Stage IV Breast Cancer


Phase I Study of Paclitaxel/Doxorubicin, Paclitaxel, and Cyclophosphamide With Peripheral Blood Stem Cell and G-CSF Support for Metastatic Breast Cancer


Phase I Study of Peripheral Blood Stem Cells (PBSC) or Isolated CD34+ Cells from Mobilized Peripheral Blood Stem Cells for Autologous Transplantation for Patients With Responsive Metastatic Breast Cancer or High Risk Stage II and III Patients

Chairperson: George Somlo. Telephone: 626-359-8111. Lead organization: Beckman Research Institute of the City of Hope. Age range: 18 to under physiologic 60.

Phase I Study of Paclitaxel/Doxorubicin/Cyclophosphamide Followed by Stem Cell Rescue in High-Risk Primary Breast Cancer and Chemotherapy-Responsive Metastatic Breast Cancer

Chairperson: George Somlo. Telephone: 626-359-8111. Lead organization: Beckman Research Institute of the City of Hope. Age range: 18 to under physiologic 60.

Phase II Study of Sequential High-Dose Cyclophosphamide, Melphalan, and Thiotepa Followed by Peripheral Blood Stem Cell Rescue in Chemotherapy-Sensitive Metastatic Breast Cancer


Phase I Study of 131I MIBG and Filgrastim to Filgrastim for Mobilization of Peripheral Blood Stem Cells for Total Body Irradiation and Thiotepa With Autologous Peripheral Blood Stem Cell Rescue for Men With Stage IIIIB or Metastatic Adenocarcinoma of the Breast


Phase III Randomized Comparison of High-Dose Chemotherapy Plus Filgrastim to Filgrastim for Mobilization of Peripheral Blood Stem Cells for Autologous Transplantation for Patients With Responsive Metastatic Breast Cancer or High Risk Stage II and III Patients


Phase II Study of Dose-Intensive Chemotherapy and Stem Cell Rescue in Patients With Inflammatory Stage IIIIB Breast Cancer

Chairperson: George Somlo. Telephone: 626-359-8111. Lead organization: Beckman Research Institute of the City of Hope. Age range: 60 and under.

Phase II Study of High-Dose Combination Chemotherapy and Autologous or Syngeneic Peripheral Blood Stem Cell Rescue Followed by Immunotherapy With Interleukin-2 and Sargramostim (GM-CSF) in Patients With Inflammatory Stage IIIIB and Responsive Metastatic Stage IV Breast Cancer


Phase I Study of High-Dose Paclitaxel/Cisplatin/
Cyclophosphamide With Cyclosporine Plus Peripheral Blood Stem Cell Rescue for Advanced Cancer  
LSU-97447, NCI-V97-1341 Phase II Study of Samarium 153 and Autologous Bone Marrow Transplantation for Stage IV Breast Cancer  
FRE-FNCLCC-PEGASE03, EU-96032 Phase III Randomized Study of Intensification With Cyclophosphamide/Thiotepa (CHUT) With Autologous PBSC Support vs No Intensification in Locally Recurrent or Metastatic Breast Cancer Responsive to Induction With Epirubicin/Fluorouracil/Cyclophosphamide (FEC 100)  
JHOC-971001004, NCI-G98-1404, J-9737 Phase II Study of Busulfan, Cyclophosphamide, and Allogeneic Bone Marrow Transplantation in Women With Metastatic Breast Cancer  
AMGEN-MGDF-951018-08 Phase II Randomized Study of Pegylated Recombinant Human Megakaryocyte Growth and Development Factor (PEG-MGDF) in Patients With High Risk Stage II, III, or IV Breast Cancer Undergoing Autologous Bone Marrow Transplantation Supported by Filgrastim  

Legend for abbreviations: 
AMGEN = Amgen, Inc. 
CCCWFU = Comprehensive Cancer Center of Wake Forest University 
CHNMC = City of Hope National Medical Center 
CLB = Cancer & Leukemia Group B 
CWRU = University Hospitals of Cleveland 
E, EST = Eastern Cooperative Oncology Group 
FHCRC = Fred Hutchinson Cancer Research Center 
FNCLCC = Federation Nationale des Centres de Lutte Contre le Cancer 
IBCSG = International Breast Cancer Study Group 
JHOC = Johns Hopkins Oncology Center 
LSU = Louisiana State University School of Medicine 
LUMC = Loyola University Medical Center 
MCV-CCHR = Massey Cancer Center 
MDA-DM = University of Texas M.D. Anderson Cancer Center 
MSKCC = Memorial Sloan-Kettering Cancer Center 
PSOG = Puget Sound Oncology Center 
SCTN = Scottish Cancer Therapy Network 
SLUMC = St. Louis University Medical Center 
STLMC = St. Luke Medical Center 
SWOG = Southwest Oncology Group 
UAB = University of Alabama Medical Center