

A.1.3.2 Technical Abstract

Phase I/II Study of Rituximab, High Dose Cyclophosphamide, and GM-CSF Based Immunotherapy for Relapsed Hodgkin's Lymphoma

NIH /OBA protocol number: 0502-698
SKCCC Protocol number: J-0528
IRB number: RPN 05-05-16-07

INTRODUCTION AND SPECIFIC AIMS

There is a clear need for more effective yet tolerable therapies for relapsed Hodgkin's lymphoma (HL). Although high dose therapy with blood or marrow transplantation (BMT) is a standard salvage approach,¹ many patients suffer disease progression or treatment-related toxicities. Immunomodulation after high dose therapy may hold promise in HL, but further definition of the appropriate immunologic targets is needed. It is proposed that profound new insights into the basic biology of Reed-Sternberg (RS) cells point to novel immunotherapeutic targets for HL, including CD20 and survivin. The following project uniquely integrates vaccine and antibody therapies for relapsed HL, with the aim of addressing fundamental questions about the ability to produce and monitor vaccine responses after rituximab and high dose therapy.

Primary objectives

- To determine the safety and tolerability of rituximab in combination with high dose cyclophosphamide and GM-CSF based immunotherapy with a novel vaccine (KGEL) for relapsed HL.
- To describe the immunologic responses to this vaccine following high dose therapy.
- To evaluate the utility of an EBV reporter system for monitoring cellular vaccine responses.
-

Secondary objectives

- To estimate the 3-year relapse-free and overall survival with this regimen.
- To describe the patterns of cellular immune reconstitution following rituximab plus high dose cyclophosphamide without stem cell reinfusion.