

A multi-center, open-label study to evaluate the safety and efficacy of pentostatin, cytoxan, and rituxan (PCR) in the treatment of previously untreated or treated, stage III or IV, low-grade B-Cell NHL

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Background: The decision to treat indolent B-cell NHL is often based on progressive disease, worsening symptoms, and increasing hematological derangement. When treatment is indicated, these lymphoproliferative disorders are very sensitive to combination chemotherapies. Combination therapy with these agents, pentostatin (P), a purine analog, cyclophosphamide (C), a DNA alkylator, and rituximab (R), an anti-CD20 monoclonal antibody, represents a promising approach in the treatment of these patients. Most regimens have utilized fludarabine (F) as the purine analog but the myelosuppression and immunosuppression of (F) combinations frequently results in severe infections. **Methods:** Eligibility criteria allow previously treated and treatment-naïve patients diagnosed with low-grade stage III/IV NHL (REAL classification) to be enrolled. Treatment consisted of intravenous infusions of P (4 mg/m²), C (600 mg/m²), and R (375 mg/m²) on day 1 of a 21-day cycle for a total of 8 cycles. Clinical evaluation was performed after cycles 2, 4, 6 and 8. Patients were stratified by disease and by prior treatment status. **Results:** The intent-to-treat (ITT) population consisted of 54 NHL patients (median age 65, range 30–86) who received a total of 330 cycles (median 6 per patient). The ECOG status was 0 (31%), 1 (58%) and 2 (12%). The overall objective response rate was 71% (CR 15%, Cru 13%, PR 43%). Eight grade 4 neutropenias were documented along with a single grade 4 leukopenia. There were a total of 3 deaths which occurred within 30 days of the last dose. The first death was due to a second primary, NSCLC, diagnosed after treatment began. The second death occurred in an 81 year-old female, who had achieved PR, and her death was due to CHF. The last death, due to MI/CAD, occurred in an 84 year-old woman with SD. **Conclusions:** This immunochemotherapeutic regimen is active in indolent Grade III/IV NHL and the incidence of significant toxicities was low. Updated trial results will be presented at the ASCO annual meeting. Future trials evaluating the use of R as maintenance therapy following this PCR regimen may also be warranted with an eye toward increasing the overall survival of patients with NHL.