

A Multi-Center, Open-Label Study To Evaluate the Safety and Efficacy of Pentostatin, Cytosan, and Rituxan (PCR) in the Treatment of Previously Untreated or Treated, Bulky Stage II, Stage III or IV, Low-Grade B-Cell NHL.

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Abstract

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 utilizing pentostatin (P), a purine analog, cyclophosphamide (C), a DNA alkylator, and rituximab (R), an anti-CD20 monoclonal antibody. P+C+R 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. Eligibility criteria allow both treated and treatment-naïve patients diagnosed with Bulky Stage II or 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 up to 10 cycles. Clinical evaluation was performed after cycles 2, 4, 6, 8 and 10 (if necessary). The intent-to-treat (ITT) population consisted of 76 NHL patients (median age 65, range 29-84) who received a total of 385 cycles (median 6 per patient). The ECOG status was 0 (64%), 1 (36%) and 2 (0%). The overall response rate (CR+Cru+PR) of the 69 evaluable patients was 72% (CR 11.6%, Cru 11.6%, PR 47.8%, SD 27.5% and PD or RD 1.4%). 12 grade 4 and 23 grade 3 neutropenias were documented. There were a total of 5 deaths due to acute myocardial infarction, NSCLC, a suspected cardiac event and 2 unknown cause of death. This immunochemotherapeutic regimen is active in indolent Grade III/IV NHL and the incidence of significant toxicities was low. 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. The results will be updated at the meeting.