The multicenter trial SAKK 37/95 of cladribine, cyclophosphamide and prednisone in the treatment of chronic lymphocytic leukemias and low-grade non-Hodgkin's lymphomas

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A multicenter trial was performed to confirm the therapeutic efficacy and the toxicity profile of the combination of cladribine, cyclophosphamide and prednisone in low-grade non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukemia (CLL). Twenty-three adults with previously treated (61%) or untreated (39%) NHL International Working Formulation A or Binet B and C CLL were administered cladribine 0.1 mg/kg/day as a subcutaneous bolus for 5 days, intravenous cyclophosphamide 500 mg/m2 on day 1, and oral prednisone 40 mg/m2 on days 1-5, every 4 weeks. Unexpected early hematological toxicities led to dose modifications for pretreated patients who received cladribine for 3 days only up to a maximum of five courses. Responses were observed in 75%, with 7 patients obtaining a complete clinical and hematological response. Median duration of complete response was 9 months. Median time to progression or relapse was 31 months. Myelosuppression and infections were dose limiting whereas posttreatment complications, including fatalities, resulted from infections. Median overall survival time from trial entry was 60 months. Activity of the combination of cladribine, cyclophosphamide and prednisone was confirmed. However, in the specific setting of a multicenter trial, unexpected fatal infectious episodes occurred in pretreated patients. Great caution is thus required in these susceptible patients and the routine use of corticosteroids should probably be abandoned.

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