Randomized trial of daily versus weekly administration of 2-chlorodeoxyadenosine in patients with hairy cell leukemia: a multicenter phase III trial (SAKK 32/98)

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Daily administration of 2-chlorodeoxyadenosine (Cladribine, CDA) is a standard treatment for hairy cell leukemia, but may cause severe neutropenia and neutropenic fever. This trial compared toxicity and efficacy of weekly versus daily CDA administration. One hundred patients were randomized to receive standard (CDA 0.14 mg/kg/day day 1-5 [Arm A]) or experimental treatment (CDA 0.14 mg/kg/day once weekly for 5 weeks [Arm B]). The primary endpoint was average leukocyte count within 6 weeks from randomization. Secondary endpoints included response rates, other acute hematotoxicity, acute infection rate, hospital admission, remission duration, event-free, and overall survival. There was no significant difference in average leukocyte count. Response rate (complete + partial remission) at week 10 was 78% (95% confidence interval (CI) 64-88%) in Arm A and 68% (95% CI 54-80%) in Arm B (p = 0.13). Best response rates during follow-up were identical (86%) in both arms. No significant difference was found in the rate of grade 3+4 leukocytopenia (94% vs. 84%), grade 3+4 neutropenia (90% vs. 80%), acute infection (44% vs. 40%), hospitalization (38% vs. 34%), and erythrocyte support (22% vs. 30%) within 10 weeks. Overall, these findings indicate that there are no apparent advantages in toxicity and efficacy by giving CDA weekly rather than daily.