Consolidation with alemtuzumab in patients with chronic lymphocytic leukemia (CLL) in first remission—experience on safety and efficacy within a randomized multicenter phase III trial of the German CLL Study Group (GCLLSG).

Abstract:

Patients with CLL responding to initial chemotherapy with fludarabine alone (F) or in combination with cyclophosphamide (FC) were randomized for treatment with alemtuzumab (30 mg i.v. TIW, 12 weeks) or observation. Of 21 evaluable patients, 11 were randomized to alemtuzumab before the study was stopped due to severe infections in seven of 11 patients. These infections (one life-threatening pulmonary aspergillosis IV; four CMV reactivations III requiring i.v. ganciclovir; one pulmonary tuberculosis III; one herpes zoster III) were successfully treated and not associated with cumulative dose of alemtuzumab. In the observation arm, one herpes zoster infection II and one sinusitis I were documented. At 6 months after randomization, two patients in the alemtuzumab arm converted to CR, while three patients in the observation arm progressed. After alemtuzumab treatment, five of six patients achieved a molecular remission in peripheral blood while all patients in the observation arm remained MRD-positive (P=0.048). At 21.4 months median follow-up, patients receiving alemtuzumab showed a significant longer
progression-free survival (no progression vs mean 24.7 months; P=0.036). In conclusion, a consolidation therapy with alemtuzumab is able to achieve molecular remissions and longer survival in CLL, but a safe treatment regimen needs to be determined.