Low-dose fludarabine with or without darbepoetin alfa in patients with chronic lymphocytic leukemia and comorbidity: primary results of the CLL9 trial of the German CLL Study Group.

This study was planned as a phase 3 trial to investigate low-dose fludarabine with or without darbepoetin alfa in older patients with previously untreated or treated chronic lymphocytic leukemia (CLL) and comorbidity. Due to slow recruitment, the study was terminated prematurely after accrual of 97 patients who, on average, were 74 years old and had a cumulative illness rating scale (CIRS) total score of 5. We report toxicity and efficacy of the study treatment. Grade 3-5 neutropenia and infection were observed in 25% and 10% of patients, respectively. Response was seen in 73% (5% complete remissions). Median event-free and overall survival was 12.2 and 44.8 months, respectively. No differences in outcome were found for patients treated with versus without darbepoetin alfa. In subjects with progressive/recurrent CLL during or after study treatment, overall survival was similar for patients receiving chemotherapy versus chemoimmunotherapy as salvage treatment.