Due to low infection rates no routine anti-infective prophylaxis is required in younger patients with chronic lymphocytic leukaemia during fludarabine-based first line therapy.

The impact of the combination therapy fludarabine plus cyclophosphamide (FC) in comparison with fludarabine alone regarding the incidence and severity of infections among previously untreated patients with chronic lymphocytic leukaemia (CLL) was evaluated within a multicentre phase III study. A total of 375 patients, up to 65 years old, were randomised between fludarabine or FC for first line therapy. No routine anti-infective prophylaxis was provided. A total of 196 infectious episodes, including 33 severe infections, were documented. In the fludarabine arm, 32.9% of the patients developed an infectious complication compared with 39.9% in the FC arm ($P = 0.2$). No difference was observed in the rate of severe infections (Common Toxicity Criteria grades III and IV) between both treatment arms. Dose reductions were performed more frequently in FC-treated patients. Granulocyte colony-stimulating factor (G-CSF) was administered due to leucopenia in 5% of all patients. A multivariate regression model identified only elevated thymidine kinase, but not the treatment arm, as a statistically independent risk factor for infections. In summary, FC was not associated with a higher rate of infections compared with fludarabine alone. No routine antibiotic or virostatic prophylaxis, or preemptive treatment
with G-CSF, is necessary in first line therapy with fludarabine-based regimens in younger patients with CLL, if adequate dose reduction is performed. The combination therapy FC is not associated with a higher rate of infections compared with fludarabine alone. No routine antibiotic or virostatic prophylaxis as well as preemptive treatment with G-CSF is necessary in first line therapy with fludarabine-based regimen in younger patients with CLL, if adequate dose reductions due to cytopenia or previous infections are performed.