

Phase II study of low-grade non-Hodgkin lymphomas with fludarabine and mitoxantrone followed by rituximab consolidation: promising results in marginal zone lymphoma.

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Source

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Abstract

The majority of patients with indolent lymphomas relapse due to minimal residual disease (MRD). In the present study, we sought to determine whether by using rituximab consolidation, for eradication of MRD, following induction chemotherapy with fludarabine and mitoxantrone (FN) combination could improve the outcome of indolent lymphomas. Patients with indolent lymphoma received fludarabine 25 mg/m² Day 1-3 and mitoxantrone 10 mg/m² on Day 1 every 28 days. Patients who attained a response (complete response, CR or partial response, PR) received four weekly doses of Rituximab 375 mg/m² 1 month and 3 months after completion of treatment. Forty-five patients were entered into this Phase II trial. The median follow-up time was 39 months. The median number of delivered cycles was 6. Fifty-three percent of patients attained a CR and 38% a PR for an overall response rate of 91%. One patient had stable disease, one had progression of the disease, whereas 2 were non-evaluable. After a median follow-up of 39 months, 32 of 46 patients (74%) are alive and disease-free. Grade III and IV toxicities included leucopenia (37%), neutropenia (28%), thrombocytopenia (7%), anemia (4%), and diarrhea (2%). Grade V toxicities included septic death in one patient and death due to hepatitis B reactivation 6 months after the last Rituximab dose in another patient. FN followed by R consolidation is a well-tolerated and active regimen in the treatment of patients with indolent lymphomas. Further follow-up is required to determine if these remissions are maintained.