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**Primary treatment of low-grade non-Hodgkin's lymphoma with the combination of fludarabine and mitoxantrone: a phase II study of the Hellenic Cooperative Oncology Group.**

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**Source**

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**Abstract**

The treatment of patients with recurrent low-grade lymphoma with the combination of fludarabine, mitoxantrone and dexamethasone has been associated with significant activity but has also caused frequent infectious complications. We designed a phase II study for previously untreated patients with the combination of fludarabine and mitoxantrone but without steroids. Our aim was to assess the activity of this combination as primary treatment for low-grade lymphoma and to avoid the additional immunosuppression induced by dexamethasone. Twenty seven patients with low-grade lymphoma received fludarabine 25 mg/m<sup>2</sup>/day i.v. on days 1-3 and mitoxantrone 10 mg/m<sup>2</sup> i.v. on day 1. The treatment was repeated every 28 days for a maximum of six cycles. Twenty patients (74%) achieved an objective response including 12 (44%) complete and 8 (30%) partial responses. The main toxicity was grade III or IV neutropenia, which occurred in 40% of patients but there were no severe opportunistic infections. The median time to progression for all patients was 32 months. With a median follow-up of 33.4 months, six patients have died and the probability of survival at 3 years is 75%. We conclude that the fludarabine and mitoxantrone regimen is safe and effective for newly diagnosed patients with low-grade lymphoma who require treatment. Prospective randomized trials are needed in order to assess the impact of this treatment on patients' survival.