

Combination of pegylated liposomal doxorubicin (PLD) and paclitaxel in patients with advanced soft tissue sarcoma: a phase II study of the Hellenic Cooperative Oncology Group.

[Bafaloukos D](#), [Papadimitriou C](#), [Linardou H](#), [Aravantinos G](#), [Papakostas P](#), [Skarlos D](#), [Kosmidis P](#), [Fountzilas G](#), [Gogas H](#), [Kalofonos C](#), [Dimopoulos AM](#).

Source

Department of Medical Oncology, Metropolitan Hospital, Ethnarhou Makariou Street, No. 9, N. Faliro, Athens 18547, Greece. dimpmp@otent.gr

Abstract

Patients with soft tissue sarcoma (STS), even after complete local disease control, often relapse locally or with distant metastases. This multicenter phase II study was conducted to evaluate the safety and efficacy of the combination of pegylated liposomal doxorubicin (PLD) and paclitaxel, as first-line treatment in patients with advanced STS. In all, 42 patients with locally advanced or metastatic STS, median age 54 years and median Eastern Cooperative Oncology Group performance status (PS) 1 were treated with PLD 45 mg m⁻² and paclitaxel 150 mg m⁻², every 28 days for a total of six cycles. Histological types included mainly leiomyosarcomas (43%), malignant fibrous histiocytomas (14%) and liposarcomas (12%). At study entry, 69% of patients had distant metastases. Overall response rate was 16%, including one complete (CR 2%) and six partial responses (PRs 14%), while an additional 14 patients had disease stabilization (SD 33%). At median follow-up 41.5 months, median time to progression (TTP) was 5.7 months with median overall survival (OS) 13.2 months. Grade 3-4 toxicities included neutropenia (17%), anaemia (15%), neurotoxicity (5%) and palmar-plantar erythrodysesthesia (9%). There were no treatment-related deaths. The combination of PLD and paclitaxel is a safe and well-tolerated regimen demonstrating modest efficacy as first-line treatment in patients with advanced STS.