

Doxorubicin alone or with ifosfamide for treating soft tissue sarcoma?

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An EORTC study published in *The Lancet Oncology* does not support administration of intensified doxorubicin and ifosfamide for palliation of advanced soft tissue sarcoma, unless the objective is to shrink the tumor.

Dr. Ian Judson of the Royal Marsden Hospital in London and coordinator of this study says, "Our clinical trial was designed to compare combination treatment with doxorubicin and ifosfamide to treatment with doxorubicin alone, and our results show that the [combination chemotherapy](#) did not improve overall survival. So, if the goal of treatment is to control the disease, then administering doxorubicin alone is appropriate. On the other hand, if the goal is to shrink the tumor before another intervention or to relieve symptoms, then combination treatment is justifiable. The observed lack of improvement in overall survival points to the need for better treatments for [patients](#) with this disease."

For some thirty years, patients with soft tissue sarcomas have been treated with doxorubicin and ifosfamide, but few studies have directly assessed whether doxorubicin should be administered alone or in combination with ifosfamide. EORTC trial 62012 assessed whether the addition of ifosfamide to doxorubicin improves survival of patients with advanced [soft-tissue sarcoma](#) compared with doxorubicin alone.

Between April 2003 and May 2010, EORTC trial 62012 randomized 455 patients aged 18 to 60 years with unresectable locally advanced or

metastatic high-grade soft-tissue sarcoma to receive either doxorubicin alone (228 patients) or intensified doxorubicin plus ifosfamide (227 patients, combination group) as first-line [treatment](#). At a median follow-up of 56 months in the doxorubicin alone group and 59 months in the combination group, no significant difference was observed in median overall survival (12.8 months [95.5% CI 10.5 - 14.3] in the doxorubicin alone group and 14.3 months [12.5 – 16.5] in the combination group; hazard ratio [HR] 0.83 [95.5% CI 0.67 - 1.03]; stratified logrank test $p = 0.076$). Median progression-free survival was significantly higher in the combination group (7.4 months [95% CI 6.6 – 8.3]) than for the doxorubicin alone group (4.6 months [2.9 - 5.6]; HR 0.74 [95% CI 0.60 – 0.90], stratified log-rank test $p = 0.003$). More patients in the doxorubicin and ifosfamide group than in the doxorubicin alone group had an overall response (26% versus 14%; p

The most common grade 3 and 4 toxic effects were all more common in the combination than in the [doxorubicin](#) alone group: leucopenia (43% versus 18%), neutropenia (42% versus 37%), febrile neutropenia (46% versus 13%), anemia (35% versus 5%), and thrombocytopenia (33% versus

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