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A RANDOMIZED TRIAL OF ADJUVANT TREATMENT OF SOFT TISSUE SARCOMAS BY EITHER RADIOTHERAPY OR RADIOTHERAPY + IFOSFAMIDE, ADRIBLASTIN AND DTIC (IFADIC) INTENSIFIED BY THE USE OF G-CSF. C. Zielinski, P. Ritschl, M. Krainer, R. Pötter, W. Dobrowsky, M. Salzer-Kuntschik, G. Amann, S. Lang, R. Windhager, R. Kotz. Departments of Clinical Oncology, Orthopedics, Radiotherapy and Clinical Pathology, University Hospital, A-1090 Vienna, Austria.

A randomized trial on the postoperative adjuvant treatment of undifferentiated (G3) soft tissue sarcomas confined to one compartment and locoregionally operable by wide/marginal resection was performed. The treatment protocol foresaw a randomization schedule which selected between either adjuvant radiotherapy (51 Gy, hyperfractionated) or adjuvant radiotherapy + cytostatic treatment consisting of Ifosfamide (1500 mg/m^2, days 1 to 4), Adriblastin (25 mg/m^2, days 1and 2) and DTIC (200 mg/m^2, days 1 to 4; IFADIC) q.6 in 14-day intervals in which G-CSF (4 µg/kg body weight) were administered on days 5-14. Recruitment was started on January 1, 1993, and is currently being continued. During this time, 30 patients were treated, from which 15 received radiotherapy and 15 radio- and chemotherapy. Preceding this treatment, all patients underwent wide/marginal resection of the primary tumor. After a mean observation period of 18±7 months, 5 patients from the radiotherapy group and 5 patients from the radio- and chemotherapy group have experienced recurrence of disease (p=0.215). All other patients have remained in complete remission. Recurrence of disease occurred on distant, visceral sites in 3 and locally in 2 of 5 patients from the radiotherapy group and on visceral sites in 2 versus locally in 3 of 5 patients from the radio- and chemotherapy group. We conclude that the addition of intensified and combined chemotherapy (IFADIC) was not superior to the administration of radiotherapy only. Thus, patients with soft tissue sarcomas with characteristics similar to those cited above should be included into clinical treatment studies before being routinely exposed to therapeutic regimens of potential toxicity.