frequent G3/4 non-haematological toxicities were asthenia (10%), nausea and vomiting (4% and 6%). Four deaths were considered treatment-related (those pts had contraindications to receive T and/or violation of dose guidelines). Efficacy (WHO criteria) in 75 STS pts was: 7 PRs and 24 SD (including 2 minor responses [MR]). Overall response rate (ORR): 10% (95% CI: 4−18); *m*PFS: 1.6 months (mo) (95% CI: 1.4−2.8), *m*OS: 10.5 mo (95% CI: 6.6−14.3) and *m* duration of response (*m*DR): 4.6 mo (95% CI: 2.1−7.1). Bone sarcoma pts (n = 25) had: 3 PR and 4 SD (including 2 MR); ORR: 12% (95% CI: 2−31) with *m*PFS: 2.1 mo (95% CI: 1.1−3.2), *m*OS: 7.1 mo (95% CI: 3.6−10.5) and *m*DR: 2.9 mo (95% CI: 2.1−3.6). The overall clinical benefit (PR+MR/SD>6mo) for all populations was 17%.
Conclusions: T given as a 3-h infusion q3wk is safe and can be given on an outpatient basis to heavily pre-treated pts with advanced sarcoma. The observed clinical benefit is noteworthy, given the degree of pre-treatment and tumour burden in this population.

9427 POSTER

Efficacy of second-line trabectedin in patients with advanced liposarcomas and leiomyosarcomas progressing despite prior conventional chemotherapy

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Background: The efficacy of trabectedin every 3 weeks, 24-h infusion (q3wk-24h) was compared vs. a weekly regimen over 3-h (qwk-3h) in an international randomized trial of 270 patients (pts) with liposarcomas and leiomyosarcomas progressing despite prior therapy with at least an anthracycline and ifosfamide. Outcomes of 1.5 mg/m^2 in the q3wk-24h arm were significantly better than those in the weekly regimen: median number of cycles 5 (1−37) vs. 2 (1−21); median time to progression (TTP) 3.7 vs. 2.3 mo. [HR: 0.734; p = 0.0302]; median progression free survival (PFS) 3.3 vs. 2.3 mo. [HR: 0.755; p = 0.0418]. Median survival (n = 175 events) 13.8 vs. 11.8 mo. [HR: 0.823; p = 0.1984] (ASCO 2007). European Commission approval was based mainly on these data. The objective of this pos hoc analysis is to present information from the subset of pts treated with trabectedin as a second-line regimen.
Methods: 93 pts received trabectedin as second line (n = 47 q3wk-24h and n = 46 qwk-3h). Median number of cycles, TTP, PFS, tumor control rate and overall survival (OS) were analyzed. Endpoints were assessed by independent review. All pts had progressed to one prior treatment with an anthracycline plus ifosfamide.
Results: In the q3wk-24h vs. qwk-3h arms median number of cycles were 6 (1−25) vs. 4 (1−14); median TTP 4.4 mo. 95% CI (2.0−7.6) vs. 3.6 mo. 95% CI (2.1−6.8) HR: 0.82 p = 0.4231; TTP at 6 mo. 41.9% 95% CI (27.3−56.5%) vs. 38.0% 95% CI (22.7−53.3%); median PFS 4.4 mo. 95% CI (2.0−7.6) vs. 3.6 mo. 95% CI (2.3−6.8) HR: 0.833 p = 0.4502; PFS at 6 mo. 41.0% 95% CI (26.6−55.4%) vs. 38.3% 95% CI (23.7−53.0%). Three (6.4%) partial responses (PR) and 23 (48.9%) stable disease (SD) (SD$\geqslant$6 mo. 27.7%) vs. 1 (2.2%) PR and 24 (52.2%) SD (SD$\geqslant$6 mo. 23.9%) were seen in the q3wk-24h vs. qwk-3h, respectively. OS at 36 mo. was 23.9% 95% CI (11.4−36.5%) vs. 16.2% 95% CI (5.3−27.0%). The safety profile of trabectedin in this subset was manageable and in line with prior experience.
Conclusions: Efficacy outcomes were better in the subset of pts receiving trabectedin after failure of first-line anthracycline + ifosfamide relative to pts with more extensive prior therapy, with similar safety profile. Consistent with the results in the overall population, longer TTP and PFS were found with trabectedin q3wk-24h.

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Experience in high-dose chemotherapy with peripheral stem cell rescue and biotherapy for young adults with high-risk Ewing/PNET sarcoma

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Background: The Protocol MMES-99 (Minsk-Moscow Ewing's Sarcoma) includes the induction chemotherapy (CT) and the consolidation (resection and/or radiation therapy (RT)) and the high-dose CT with peripheral stem cell rescue (PSCR) and biotherapy with interleukin-2 (Roncoleukin®). The objective of this study is evaluation of tolerance and efficacy of the MMES-99 Protocol in young adults.
Materials and Methods: Induction phase consists of 5 or 6 courses of CT, A–B–A–B–A (course A: cyclophosphamide 4.2 g/m^2 + doxorubicine 75 mg/m^2 + vincristine 3 mg/m^2 (1.5 mg/m^2, days 1 and 8); course B: ifosphamide 12 g/m^2 + etoposide 500 mg/m^2). The harvest of PSC was performed after the 2nd−3rd course. Local RT (a total target dose (TTD) of 51 Gy, a hyperfractionated schedule) or surgery was administered after the 5th course, followed by the high-dose CT. In case of prolonged intervals between the courses of local RT (more than 4 weeks), the patients received the course C (vincristine 3 mg/m^2 + cyclophosphamide 4.2 g/m^2). Patients with pulmonary metastases were administered RT on lungs after the 2nd course (TTD 12 Gy). High-dose CT: busulfan 16 mg/kg, thiophosphamide 600 mg/m^2, melphalan 140 mg/m^2. We present the results of treatment of 10 patients (the median age 21.5 years (range 17−26)). In two cases the treatment was started in progression disease. Lesions: 2 – spine, 1 – spine+lungs, 1 – skull, 2 – pelvic bones (505 ml and 393 ml), 1 – clavicle (450 ml)+lungs, 1 – humerus (1290 ml), 1 – femoral bone (160 ml), 1 – multicentre involvement of bones+lungs. EWS and EWS-ERG genes in blood and bone marrow were negative before harvest of PSC.
Results: 54 courses of induction CT were administered. Harvest of PSC and subsequent high-dose CT were performed in 8 patients (median value of CD34 $3.5 \cdot 10^6$/kg; median number of nucleated cells $4.0 \cdot 10^8$/kg). Two patients did not undergo harvest of PSC due to infectious complications and no response to induction therapy. Five patients received Roncoleukin®. A total of 66 immunotherapy courses were administered, the mean single dose of Roncoleukin® was 2.7 mg, the mean protocol dose 49.5 mg. The immediate clinical effect was 90%. The progression-free survival rate was 0.67 ± 0.27 (median follow-up before progression 20.0 months). Grade 4 induction toxicity (CTCAE): leukopenia 81.4%, thrombocytopenia 29.6%, anemia 7.4%, infectious complications 16.7%.
Conclusion: Intensive induction therapy followed by high-dose CT and interleukin-2 biotherapy for young adults (before 30 years) with Ewing's sarcoma is a treatment of choice with adequate supportive therapy.

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Long-term toxicity in survivors of bone tumors diagnosed at adult age: a plea for systematic screening and timely intervention

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Background: It is well known that survivors of childhood cancer may experience late toxicity of therapy. Survivors of bone tumors appear the most severely affected, which is explained by the specific combination of cytotoxic drugs and often major surgery. We know of no systematic screening for late events in survivors of malignant Ewing's sarcoma (ES) and osteosarcoma (OS) treated at adult age and therefore initiated the following study.
Patients and Methods: Patients who had been diagnosed with OS or ES at age 16 or over and treated at adult departments of the Radboud University Nijmegen Medical Center between 1982 and 2007 were identified. Those who are currently alive and relapse-free were invited for a systematic screening for late toxicity, consisting of history taking and physical examination, Multi Gated Acquisition (MUGA) scan, echocardiogram, dual energy x-ray absorptiometry (DEXA), audiogram,