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High dose methotrexate for pediatric high grade glioma: results of the HIT-GBM-D Pilot study.

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Abstract

We conducted a phase II study to test methotrexate (5 g/m²), as a single agent prior to radiochemotherapy for pediatric high-grade glioma and diffuse intrinsic pontine glioma. Thirty patients (19 male, median age 10.8) were enrolled. Tumors were located as follows: cortex 10, pons 7, other 13. Tumor resection was classified as gross total in 6, subtotal in 6, partial in 4, biopsy in 11 and not performed in 3. WHO grading of the histology was: IV: 11, III: 12 and II: 3. Patients received methotrexate 5 g/m² in 24-hour infusions on days 1 and 15. Subsequently 54 Gy radiation was administered with simultaneous chemotherapy including cisplatin, etoposide, vincristine and ifosfamide as previously described. Eight 6-weeks cycles of maintenance chemotherapy consisted of vincristine 1.5 mg/m² on days 1, 8 and 15; lomustine 100 mg/m² on day 2 and prednisone 40 mg/kg on days 1-17. Event-free survival rates in the whole group of 30 patients were: 43, 20, and 13% after 1, 2 and 5 years, respectively. The response evaluation after methotrexate was available in 19 of the 24 patients who started treatment with measurable disease: CR: 0, PR: 1, SD 18, PD: 0. After radiochemotherapy the response of 24 patients with measurable disease was CR: 1, PR 10, SD 12, PD 1. Both response and event-free survival were superior to the control group of 330 patients treated in various protocols of the same cooperative group. In subgroup analyses the use of dexamethasone during early treatment was linked to poor event free survival. Giving two cycles of high-dose methotrexate prior to radiochemotherapy was feasible, and the approach was taken forward to a randomized phase III trial.

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