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1: [Br J Cancer](#). 2009 Jan 27;100(2):291-7. Epub 2009 Jan 6.



A phase III trial of topotecan and whole brain radiation therapy for patients with CNS-metastases due to lung cancer.

[Neuhaus T](#), [Ko Y](#), [Muller RP](#), [Grabenbauer GG](#), [Hedde JP](#), [Schueller H](#), [Kocher M](#), [Stier S](#), [Fietkau R](#).

Johanniter-Krankenhaus, Bonn, Germany.

Brain metastases represent an important cause of morbidity in patients with lung cancer and are associated with a mean survival of less than 6 months. Thus, new regimens improving the outcome of these patients are urgently needed. On the basis of promising data raised in a phase I/II trial, we initiated an open, randomised, prospective, multicentric phase III trial, comparing whole brain radiation therapy (WBRT; 20 x 2 Gy) alone with WBRT+topotecan (RCT; 0.4 mg m⁻² day⁻¹ x 20). A total of 320 patients with CNS-metastases due to SCLC or NSCLC were projected. The primary end point was overall survival, whereas second end points were local response and progression-free survival. However, until the cutoff date of study completion (i.e., a study duration of 34 months), only a total of 96 (RCT:47, WBRT:49) patients had been recruited, and so an analysis was performed at that time point. Although the numbers of grade 3/4 non-haematological toxicities (besides alopecia 115 (RCT/WBRT: 55 out of 60) were evenly distributed, the 25 haematological events occurred mainly in the combined treatment arm (24 out of 1). Local response, evaluated 2 weeks after treatment, was assessable in 44 (RCT/WBRT: 23 out of 21) patients, showing CR in eight (3 out of 5), PR in 17 (11 out of 6), SD in 14 (8 out of 6) and PD in five (1 out of 4) patients (all differences n.s.). Neither OAS (RCT/WBRT: median (days)): 87 out of 95, range 3-752/4-433; HR 1.32; 95% CI (0.83; 2.10)) nor PFS (median (days)): 71 out of 66, range, 3-399/4-228; HR 1.28, 95% CI (0.73; 2.43) differed significantly. On the basis of these results and the slow recruitment, a continuation of the study did not seem reasonable. The available data show no significant advantage for concurrent radiochemotherapy for patients with lung cancer; however, the recruited number of patients is too low to exhibit a small advantage of combined treatment.

Publication Types:

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