Purpose: Patients with brain metastases are often excluded from clinical trials, but it is unclear if they pose an enhanced risk.

Experimental Design: We reviewed the records of 1,181 consecutive patients with and without brain metastases treated in the Phase I Clinical Trials Program.

Results: Ninety-three patients had brain metastases at the time of referral. Their median age was 54 years; median follow-up, 8 months. The rates of stable disease ≥ 4 months/partial/complete response in patients with and without brain metastases were 17% and 27%, respectively (p=0.03). Although the median survival for patients with brain metastases was shorter than for that of patients without brain metastases (7.5 vs. 10.3 months; p = 0.002), in multivariate analysis the presence of brain metastases was not an independent factor predicting survival. There was no difference in time-to-treatment failure (1.74 vs. 1.84 months, respectively; p = 0.61) or in Grade 3-4 toxicity (including neurologic) between patients with and without brain metastases (12% vs. 10%, p = 0.77).

Conclusions: The rates of survival and response of patients with brain metastases were lower than those for other patients in the Phase I setting, but the presence of brain metastases was not an independent prognostic factor predicting survival, indicating that other covariates that co-exist with brain metastases were more significant. Time-to-treatment failure for patients with brain metastases was not decreased, nor was the incidence of serious side effects (including neurologic toxicity) increased, suggesting that these patients should be eligible for early clinical trials.

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