

Abstracts

ATCT-35. QUALITY OF LIFE, COGNITIVE FUNCTION AND FUNCTIONAL STATUS IN THE EF-14 TRIAL: A PROSPECTIVE, MULTI-CENTER TRIAL OF TTFIELDS WITH TEMOZOLOMIDE COMPARED TO TEMOZOLOMIDE ALONE IN PATIENTS WITH NEWLY DIAGNOSED GBM

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BACKGROUND: Tumor Treating Fields (TTFIELDS) are an anti-mitotic, electric-physical treatment modality. An interim analysis of the phase 3 trial comparing TTFIELDS with maintenance temozolomide (TTFIELDS/TMZ) showed superior progression free and overall survival compared to temozolomide alone (TMZ alone) in patients with newly diagnosed GBM. **METHODS:** After completion of radiotherapy with concomitant temozolomide, patients were randomized (2:1) to TTFIELDS/TMZ or TMZ alone. The main trial endpoints were progression-free survival (PFS) and overall survival (OS). Here we report the quality of life (EORTC QLQ C-30 / BN20), Karnofsky performance scores (KPS) and minimal status exam (MMSE) results in the interim analysis of the first 315 patients randomized, with a median follow-up of 38 months (range 18-60). **RESULTS** (intent-to-treat): 210 patients were randomized to TTFIELDS/TMZ and 105 patients to TMZ alone. Patient characteristics were balanced. Median PFS was 7.1 and 4.0 months [Hazard ratio (HR) 0.62, $p = 0.001$], respectively and OS from randomization was 19.6 and 16.6 months (HR 0.74, $p = 0.034$), respectively, both favoring TTFIELDS/TMZ. Global health status improved in patients treated with TTFIELDS/TMZ (change from baseline to 3 months [CFB3] = +24% and change from baseline to 6 months [CFB6] = +13%), whereas a decrease was seen in patients treated with TMZ alone (CFB3 = -7% and CFB6 = -17%). A full analysis of all domains of the QLQ C-30/BN-20 will be presented. No differences in KPS or MMSE was seen between treatment groups over time. **CONCLUSIONS:** Maintenance TTFIELDS/TMZ provides a clinically and statistically significant improvement in progression-free and overall survival in newly diagnosed GBM. Quality of life was not adversely affected by the continuous use of TTFIELDS and may be improved in some domains of the EORTC QLQ C-30 and BN20. Cognitive and functional capabilities were not impeded by the addition of TTFIELDS to TMZ therapy.