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A phase 2, open label, clinical trial of pre-surgical and adjuvant treatment of recurrent glioblastoma with tremelimumab and durvalumab alone and in combination

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Aims and scope

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Abstract

Purpose

Survival is poor for patients with recurrent glioblastoma. We prospectively investigated the use of tremelimumab (CTLA-4 inhibitor) and durvalumab (PD-L1 inhibitor) given pre- and post-surgery to assess clinical activity and safety, and to understand the intratumoral immunologic changes. This report focuses on clinical outcomes.

Methods

Recurrent glioblastoma patients were randomized to either: Arm 1, tremelimumab (75 mg every 4 weeks IV); Arm 2, durvalumab (750 mg every 2 weeks); or Arm 3, combination (tremelimumab

75 mg every 4 weeks for 7 doses then every 12 weeks along with durvalumab 750 mg every 2 weeks). Eligible patients received treatment 14 days prior to surgery, then underwent clinically indicated resection, followed by adjuvant treatment starting within 28 days after surgery.

Results

Thirty-one patients were evaluable. Median OS and PFS for the entire cohort was 8.9 months (95% CI, 7.5–14.2) and 3.2 months (95% CI, 3.0-4.1), respectively. Median OS for Arm 1 was 7.5 months (95% CI, 2.3–14.7), 13.2 for Arm 2 (95% CI, 2.6–28.0), and 7.9 (95% CI, 4.8–14.2; $P = 0.33$) for Arm 3. Treatment was well tolerated. One patient developed grade 3 colitis while 2 patients had grade 2 dermatitis. Ten patients had grade 3 hypertension, 4 patients had grade 3 hyperglycemia, and 2 patients had wound complications. There were no treatment related deaths or severe immune related toxicities.

Conclusion

The combination of tremelimumab and durvalumab is safe in recurrent glioblastoma though there was no statistical improvement in survival. This data aligns with prior studies showing a lack of benefit with checkpoint inhibitors.

Trail registration

ClinicalTrials.Gov Registration NCT02794883. Registration Date 6/9/2016.

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