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A phase I clinical trial of sonodynamic therapy combined with temozolomide in the treatment of recurrent glioblastoma

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Abstract

Purpose: The prognosis of recurrent glioblastoma (rGBM) is poor, and there is currently no effective treatment strategy. Sonodynamic therapy (SDT) is a new method for cancer treatment that uses a combination of low-frequency ultrasound and sonosensitisers to produce antitumor effects, which have shown good therapeutic effects in preclinical studies. Therefore, we initiated an open, prospective pilot study to evaluate the safety, tolerability, and efficacy of SDT for the treatment of rGBM.

Methods: Nine patients with rGBM were enrolled who had received multiple treatments, but the nidus continued to progress without additional standard treatments. After MRI localisation, porphyrin drugs were injected, and intermittent low-frequency ultrasound therapy was performed for five days.

Results: None of the nine patients in this clinical trial showed any clinical, neurological, haematological, or skin-targeted adverse effects associated with SDT. After the completion of the trial, one patient maintained stable disease, and eight patients experienced disease progression. Among the eight with progressive disease, the median progression-free survival time was 84 days. Four patients died, and the median overall survival duration after recurrence was 202.5 days.

Conclusion: The number of patients in this study was small; therefore, a long-term survival benefit was not demonstrated. However, this study suggests that SDT has potential as a treatment for rGBM and warrants further exploration. Trial information: Chinese Clinical Trial Registry (<http://www.chictr.org.cn/>): ChiCTR2200065992. November 2, 2022, retrospectively registered.

Keywords: Low-frequency ultrasound; Recurrent glioblastoma; Sonodynamic therapy; Sonosensitiser.

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