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# Investigator-led clinical trial of boron neutron capture therapy system for recurrent high-grade meningiomas after radiation therapy: Randomized phase II study

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## Abstract

**Background:** High-grade meningiomas (HGMs) recurring after X-ray treatment show poor prognosis. We assessed the effectiveness and safety of boron neutron capture therapy (BNCT) in patients with refractory recurrent HGMs.

**Methods:** This phase II investigator-led randomized controlled trial utilized an accelerator-based BNCT system to treat refractory recurrent HGMs. Patients were randomly assigned in a 2:1 ratio to the BNCT (12 patients) and control (6 patients) arms. Progression-free survival (PFS) judged by an independent third-party committee was the primary endpoint and PFS judged by the investigators and overall survival of the BNCT arm were the secondary endpoints. The control arm received rescue BNCT if they show disease progression.

**Results:** Three and two patients with World Health Organization (WHO) grade 3 disease were assigned to the BNCT and control arms, respectively; the remaining patients had WHO grade 2 disease. Median PFS (primary endpoint) was 14.4 months (95% confidence interval (CI): 7.9-26.4) in the BNCT arm and 1.4 months (95% CI: 1.0-9.0) in the control arm. Median PFS (secondary endpoint) was 14.7 months (95% CI: 7.6-22.8) in the BNCT arm and 1.5 months (95% CI: 1.0-9.0) in the control arm. The differences were statistically significant (log-rank test,  $P = 0.0157$  and  $P = 0.0002$ , respectively). Five patients in the control arm received rescue BNCT. The objective response rate in the BNCT arm was 27.3%.

**Conclusions:** BNCT is an effective treatment for refractory recurrent HGMs. Compared with conventional therapy, PFS in both primary and secondary endpoints were considerably improved.

**Keywords:** accelerator; boron neutron capture therapy; boronophenylalanine; clinical trial; high-grade meningioma.

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