

AB012. A phase III randomized trial of gross total resection versus possible resection of fluid-attenuated inversion recovery (FLAIR) hyperintensity lesion on magnetic resonance image for newly diagnosed supratentorial glioblastoma (JCOG2209)

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Background: Complete resection of contrast-enhanced lesions [gross total resection (GTR)] without severe neurological deficits has been generally accepted as the goal of surgery. However, it remains unclear if additional resection of surrounding fluid-attenuated inversion recovery (FLAIR) hyper-intense lesions combined with GTR (FLAIRectomy)

has survival advantage of primary glioblastoma patients. Multicenter, open-label, randomized phase III trial was commenced to confirm the superiority of FLAIRectomy to GTR alone followed by radiotherapy with concomitant and adjuvant temozolomide in terms of overall survival (OS) for primary glioblastoma *IDH*-wildtype patients. This trial investigates not only survival but also postoperative neurological and neurocognitive deficits in detail.

Methods: We assumed a 2-year OS of 50% in the GTR arm and expected a 15% improvement in the FLAIRectomy arm. A total of 130 patients is required with a one-sided alpha of 5%, power of 70%, and will be accrued from 49 Japanese institutions in 4 years and follow-up will last 2.5 years. Patients aged 18–75 years will be registered and randomly assigned to each arm with 1:1 allocation. The primary endpoint is OS, and the secondary endpoints are progression-free survival, frequency of adverse events, proportion of Karnofsky performance status preservation, proportion of National Institutes of Health stroke scale preservation, proportion of mini-mental state examination preservation and proportion of health-related quality of life preservation. The Japan Clinical Oncology Group Protocol Review Committee approved this study protocol in May 2023. Ethics approval was granted by the National Cancer Center Hospital Certified Review Board. Patient enrollment began in July 2023.

Results: If FLAIRectomy is superior to GTR alone, aggressive surgery will become a standard surgical treatment for glioblastoma with resectable contrast-enhanced lesion.

Conclusions: Registry number: jRCT1031230245. Date of registration: 19/July/2023. Date of first participant enrollment: 28/July/2023.

Keywords: Glioblastoma; fluid-attenuated inversion recovery hyper-intense lesions combined with gross total resection (FLAIRectomy); gross total resection (GTR)

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://cco.amegroups.com/article/view/10.21037/cco-24-ab012/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics board of National Cancer Center Hospital Certified Review Board (No. T2023003) and informed consent was obtained from all individual participants.

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