## **ABSTRACT**

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Granulocyte-macrophage colony stimulating factor enhances efficacy of nimustine rendezvousing with temozolomide plus irradiation in patients with glioblastoma.

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BACKGROUND: Glioblastoma is the most common and most aggressive type of primary brain tumor.

OBJECTIVE: The aim of this study was to investigate the efficacy and safety of intranasal granulocyte-macrophage colony stimulating factor (GM-CSF) administration combined with chemoradiotherapy in patients with glioblastoma who underwent surgery.

METHODS: Ninety-two patients were randomly divided into two groups: a control group (n= 46), who received radiotherapy with adjuvant local delivery of nimustine hydrochloride (ACNU) and systemic administration of temozolomide, and an intervention group (n= 46), who received intranasal GM-CSF prior to each cycle of adjuvant chemotherapy in addition to the treatment of the control group. Karnofsky performance status (KPS) scores, progression-free survival (PFS), overall survival (OS), and adverse effects were calculated and compared between the two groups.

RESULTS: Compared with the control group, the intervention group had longer PFS (7.8 vs. 6.9 months, P= 0.016) and OS (19.2 vs. 17.1 months, P= 0.045, without adjustment for interim analyses). The KPS scores were also higher in the intervention group than in the control group after 6 months (84.35  $\pm$  8.86 vs. 80.65  $\pm$  7.72; t= 4.552, P= 0.036). Furthermore, the patients in the intervention group had lower incidence of neutropenia and thrombocytopenia (8.7% vs. 29.5%, P= 0.012; 8.7% vs. 18.2%, P= 0.186). Other adverse events were similar in both groups, and most adverse events were grade I/II and resolved spontaneously.

CONCLUSION: Intranasal GM-CSF enhances the efficacy of the local ACNU administration combined with oral temozolomide chemotherapy. The survival and performance status were significantly improved in patients with glioblastoma after surgery. Additionally, the GM-CSF therapy was able to reduce the occurrence of chemotherapy-related neutropenia and thrombocytopenia.

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