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Session PO.CT03.01 - Phase III Clinical Trials

CT224 / 3 - Multi-institutional randomized phase-3 trial comparing cancer stem cell-targeted vs physician-choice treatments in patients with recurrent high-grade gliomas (NCT03632135)

April 12, 2022, 1:30 PM - 5:00 PM | Section 35

Presenter/Authors

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Disclosures

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Abstract

Background: Clinical outcomes in patients with recurrent high-grade glioma (HGG) remain poor. Cancer stem cells (CSCs) have been implicated in metastasis, treatment resistance and recurrence of HHGs. We have shown in several clinical studies that anti-CSC-directed therapy provides benefits in many cancer types; however, this is the first report of a randomized clinical trial evaluating it for recurrent HGGs. Objective: Determine whether CSC-targeted cytotoxic agents selected by ChemoID assay-guided therapy improves survival in patients with recurrent HGG.

Design, Settings, and Participants: In this parallel-group, randomized, phase-3 clinical trial, patients at 13 clinical sites in the USA with grade-III/IV recurrent glioma (2016 WHO guidelines) were randomized 1:1 to either ChemoID assay-guided therapy or physician-choice therapy, and then treated and followed until unacceptable toxic effects, hospice, or death.

Main Outcomes and Measures: The primary endpoint was overall survival (OS).

Results: Combined median follow-up was 9 months. Median OS (mOS) was 12.5 months (95% CI, 10.2-14.7) in the ChemoID assay-guided group vs 9 months (95% CI, 4.2-13.8) in the physician-choice group (log-rank $P = .010$). Risk of death was significantly lower in the ChemoID assay group (HR = 0.44; 95% CI, 0.24-0.81; $P = .008$). Median progression free survival (PFS) was 10.1 vs 3.5 months (95% CI, 4.8-15.4 vs 1.9-5.1) (HR, 0.25; 95% CI, 0.14-0.44; $P < .001$).

Conclusions and Relevance: Primary endpoint was met in this randomized clinical trial. The mOS was 3.5 months longer in the ChemoID assay-guided group vs the physician-choice group demonstrating the clinical advantage of treating HGG patients using CSC personalized therapy.